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NEXT STEPS FOR PATIENT SAFETY: ASSURING HIGH VALUE HEALTH CARE ACROSS ALL SITES OF CARE

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BEFORE THE

SPECIAL COMMITTEE ON AGING

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CONTENTS

NEXT STEPS FOR PATIENT SAFETY: ASSURING HIGH VALUE HEALTH CARE ACROSS ALL SITES OF CARE

MONDAY, JULY 2, 2012

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Hartford, CT.

The Committee met, pursuant to notice, at 1:06 p.m. in the Legislative Office Building, 300 Capitol Ave., Hon. Richard Blumenthal, presiding.

Present: Senator Blumenthal [presiding].

OPENING STATEMENT OF SENATOR RICHARD BLUMENTHAL

Senator BLUMENTHAL. Good afternoon. I have the great pleasure and honor of convening this special field hearing of the Committee on Aging, and I want to welcome everyone here, all of the advocates, the experts, the citizens and elected officials. I see one here, Senator Edith Prague. Thank you for being with us today.

[Applause.]

Certainly one of the experts, advocates, and great citizens of our state on this issue and so many others.

We are going to begin with a video that the Hamilton family very, very graciously has helped us put together, and then I'll make an opening statement. We're then going to ask Alice Bonner of the Department of Health and Human Services to speak to us, and then take a second panel consisting of some experts whom I will introduce at the time.

So why don't we begin with the video?

[Videotape played.]

I thank the Hamilton family again for sharing that story with us. Anybody who knows about T. Stewart Hamilton knows that his granddaughter was actually quite modest about his achievements and his stature in the community. For many, many years he was well known as a leader in the profession and an advocate for better health care in all of Connecticut, as well as an administrator at the Hartford Hospital, and I want to thank his family for so graciously sharing the story of their grandfather, T. Stewart Hamilton, who leaves a legacy and a story. I think he would have supported and approved of what we're going to do and what we're going to hear today.

I want to thank Alice Bonner for making the trip, as well as my brother, David Blumenthal, who are from outside of Connecticut. But the reason for having this hearing in Connecticut is that our

hospitals and our providers really have been at the forefront of caring about this issue of patient safety. As you'll hear from Susan Davis and others, our hospitals and our providers have made patient safety a priority. So I can think of no better place to have this hearing, and I'm very proud to do it here.

At the same time, one of the reasons we're doing it here and one of the reasons that Connecticut hospitals and providers and doctors have been so foresighted and vigorous in this effort is that we have so far to go. We have a lot of work to do. Some of the statistics nationally are absolutely staggering.

Today, an estimated 100,000 people die every year from hospital-acquired infections, at an estimated cost of $28.4 to $45 billion. That's billion, with a B. Medication errors alone harm an estimated 1.5 million people every single year, costing $3.5 billion in extra medical expenses. One in four seniors will be discharged to a nursing home and then readmitted to a hospital within 30 days, costing Medicare more than $4 billion every year, and 50 percent of all those readmissions are avoidable. The costs can be saved.

The Office of the Inspector General of the U.S. Department of Health and Human Services found in 2010 that one in seven Medicare patients are injured during hospital stays. One in seven Medicare patients nationwide are injured in hospital stays. That's a staggering number. An average of one in five Americans, 22 percent, report that they or a family member have experienced a medical error of some kind.

When we're talking about patient safety, we're talking about a problem that affects every family, literally every person in Connecticut and the country, and the work ahead should have the kind of priority that Connecticut providers and hospitals are giving it. Those kinds of numbers do not capture what you've just seen about a single man, a single person, a family that bears the burden and the grief and struggle of patient safety problems.

It really isn't about numbers; it's personal. It's not only about statistics. It's individual lives lost and suffering created. It was personal to T. Stewart Hamilton's granddaughter, as you've seen, who was brave enough to share her story. It was personal to Lorraine Purowski of South Windsor, whose husband underwent successful surgery for cancer, only to later pass away from an infection acquired afterwards. He had successful surgery for cancer. He passed away from the hospital-acquired infection afterwards. And it was personal to Marilyn Jasmine, an insulin-dependent diabetic who acquired a treatable infection after surgery, but the nursing home misplaced doctor's orders for antibiotics. She lives with the consequences of an infection that spread out of control before the mistake was realized, and she was severely hurt as a result.

We all have a stake in this problem. The Affordable Care Act and the HITECH Act are two measures designed to help address these issues, and the witnesses today who will have speak to us can speak not only to the problem but also to the solutions, because there are things we can do that will make a difference.

Every single hospital in the State of Connecticut is now part of an initiative begun by the Administration in April called the Partnership for Patients, which commits to dramatic reductions in hospital infections and readmissions. They believe that the Partner-

ship's efforts alone will save 60,000 lives and 10 billion in Medicare dollars in the next three years, and more than 50 million Medicare dollars over the next 10 years.

So these problems, those savings of 50 billion—not 50 million—50 billion Medicare dollars are achievable. The kinds of efforts that we can document in this state that we can achieve can be a model for the country. Again I want to thank the experts who are here today to talk about them, beginning with Alice Bonner, who is Director of Survey and Certification for Nursing Homes at the Center for Medical and Medicaid Services. She will open our discussion on an area that is particularly relevant to our Baby Boomers. She has a background in this area, a distinguished resume, and a background including expert work in many of the areas that are relevant here.

Her work now is to oversee certification and review of all Medicare-participating nursing homes in the United States. She has also been a geriatric nurse practitioner for the past 20 years, and she has focused her research efforts on both nursing home quality and development of patient safety culture in health care organizations.

Thank you very much for being with us.

[Applause.]

STATEMENT OF ALICE BONNER, DIRECTOR, DIVISION OF NURSING HOMES, SURVEY AND CERTIFICATION GROUP, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, BALTIMORE, MD

Ms. BONNER. I brought with me some photos that are 30 years old, from when I was a nursing assistant, which is how I got started working in nursing homes. So when you say it's personal, even though I'm representing CMS today, I want you to know that this is very personal for me as well in my 30-year journey in nursing and nursing homes.

So thank you, Senator Blumenthal, for the opportunity to appear today to discuss CMS' efforts to improve patient safety in nursing home residents. Nursing homes play an important role in health care today. More than 3 million Americans rely on services provided by nursing homes at some point during the year, and 1.4 million Americans reside in the nation's 15,800 nursing homes on any given day. Those individuals and an even larger number of their families and friends must be able to count on nursing homes to provide safe, reliable, high-quality care.

To ensure that nursing homes meet both Federal and state standards, CMS conducts initial and ongoing inspections of all facilities participating in the Medicare and Medicaid programs. The survey and certification process plays a critical role in ensuring basic levels of quality and safety for Medicare and Medicaid beneficiaries by monitoring nursing home compliance with Federal and state requirements.

Within the survey and certification group, the Division of Nursing Homes focuses on optimizing the health, safety, and quality of life for people living in nursing homes through close collaboration with other divisions as well, and over 5,000 Federal and state sur-

veyors conduct on-site surveys of certified nursing homes each year to assure basic levels of quality and safety for beneficiaries.

So prior to becoming the Director of the Division of Nursing Homes, I did work as a nurse practitioner in clinical practice in the State of Massachusetts for 20 years, and I'm very well aware of the importance of interdisciplinary partnerships in nursing home care where safe, reliable care depends on these close collaborations among nurses, nursing assistants, physicians, therapists, pharmacists, really the entire interdisciplinary team, most importantly the residents and families at the center of that care.

I've also seen firsthand the importance of balancing safety with autonomy and choice, and an ability for residents to really have a say in their daily routines and basic human rights.

So CMS encourages facilities to examine their organizations' values and structures and practices so that, as a nation, we can transform these very institutional settings that they've been for so long into person-centered environments where individuals are really recognized and respected. We know that that will improve the resident's and family's experience of care, and may also reduce staff turnover and improve care practices as well.

So today I'd like to highlight some recent specific activities that CMS has undertaken to improve quality and safety for nursing home residents in the areas of dementia care and anti-psychotic medication use, managing fall risk, nursing home oversight of special focus facilities, quality assurance and performance improvement, and care transitions.

So in terms of dementia care and anti-psychotic use, CMS has implemented substantial improvements to the survey and certification process to help address concerns about over-utilization of anti-psychotic medications. CMS revised guidelines in 2006 clarifying a number of aspects of medication management and emphasizing that residents have the right to be free from being prescribed unnecessary medications.

Current work on surveyor training focuses survey teams on a number of key processes, including the requirement that providers must try non-pharmacologic interventions first in order to manage behaviors before using medications to address them.

On May 30th, CMS announced the CMS National Partnership to Improve Dementia Care: Rethink, Reconnect, Restore. So rethink means rethinking how we approach dementia residents in nursing homes; reconnect means connecting with them as an individual, as a person, so you know enough about them to prevent some of these behaviors; and restore means restoring quality of life.

This initiative includes raising public awareness, strengthening regulatory oversight, providing technical assistance and training to nursing homes and prescribers, improving public reporting to increase transparency, and conducting research. And we've set a national goal to reduce the use of anti-psychotic medications in long-stay residents with dementia by 15 percent by the end of December 2012.

In terms of managing fall risk, CMS is attempting to reduce the number of injurious falls sustained by nursing home residents. A new quality measure on nursing homes this summer will report the percentage of falls with serious injury in nursing home residents by

facility. These data will enable professional associations, culture change coalitions, quality improvement organizations and others to target technical assistance and fall risk reduction in these facilities, so tailoring those programs to see what the problems are related to falls, which is a multi-factorial problem. And surveyors will review resident falls and will continue to enforce requirements for safety around accidents and supervision.

In terms of nursing home oversight of special focus facilities, CMS created the special focus facility program in 1998, and it was part of the Nursing Home Oversight and Improvement Program under the Clinton Administration. The purpose of the SFF program is to decrease the number of persistently poor performing nursing homes by directing more attention to nursing homes with a record of poor survey performance. Through collaboration with the states, CMS is working to continually improve the SFF program, and improvements since 2004 include increasing the number of facilities that are on the program, providing more data to the states so they can target the facilities to come into the program, and posting data on Nursing Home Compare so that consumers have information about which facilities are special focus facilities.

In terms of quality assurance and performance improvement, another initiative under the Affordable Care Act, the Affordable Care Act directed CMS to mobilize best practices in nursing home quality and to identify technical assistance to enhance nursing home quality and performance using a systems approach. CMS is currently working to roll out a new national initiative that includes development of QAPI standards and technical assistance that will enable facilities to implement those standards. QAPI tools, resources and technical assistance, including an interactive website, are currently being tested in a demonstration project and will be available to all nursing homes later this summer. A new QAPI regulation will enable the surveyors to then go and see if the nursing homes are implementing their QAPI plan, whether it's adequate protection for patient safety.

And finally, in terms of care transitions, currently transitions in care from one setting to another are very often fragmented. So someone in the hospital sending a resident to the nursing home doesn't necessarily transfer the information that the nursing home needs to take care of that person; and similarly, somebody going back to the hospital from the nursing home, the hospital emergency department doesn't always get the information that they need to really care for that person.

So in terms of this lack of communication, it's certainly responsible for medication errors and other adverse events, and as you mentioned, the unnecessary re-hospitalizations that we see.

So the survey and certification group is currently revising our guidelines and regulatory requirements for resident transfers so that we can better focus on what is the information that we need, and working with the Office of the National Coordinator so that the elements of data that we really require are being looked at, and what nursing homes need is part of that entire discussion. So the Division of Nursing Homes is also working with its partners to develop new quality measures that will track 30-day hospital readmissions on newly-admitted nursing home residents.

So in conclusion, we appreciate the work of the committee and the support in terms of improving quality and safety for all of our individuals across the country in every health care setting, but particularly the work that you're doing around nursing homes. So, thank you very much.

Senator BLUMENTHAL. Thank you for that statement. While I was reading the prepared text last night, one of the thoughts that occurred to me was whether, in the course of those site visits, is there any kind of notice given before you actually arrive there? What's the standard procedure?

Ms. BONNER. The standard procedure is that there is not notice given. These are supposed to be visits where the facility should be doing the same thing all the time for all their residents to promote safety. It shouldn't make a difference when the regulators come in.

However, it's important that these visits be unannounced. So because they have to occur on a cycle—in other words, they're annual visits—the facilities have some sense of what they sometimes refer to as "the window." So within a period of months, they have a sense that the regulators are likely to be coming. However, they're not supposed to be announced visits because, again, we want facilities—and facilities and providers are teaching, the associations are teaching their own members that the care should be the same, the quality should be the same all during the year.

Senator BLUMENTHAL. And how many people go to visit each of the sites?

Ms. BONNER. So the typical survey team—it's a team, and there's a team leader, and there are three to four for an average size facility, a 150-bed facility or so. A very small facility, there might be two or three surveyors on the team. But it's important, the way the survey works, some people go and look at the kitchen, some people look at infection control, some people look at the medication paths. So it does take a team of people, and also they're looking to make sure they get out on all of the different units, and then they come back and compare notes.

So there's a period of time at the end where there's a conference and people say, well, did you see a problem with falls on your unit? And someone else says, yes, I saw that on my unit. That leads them to sometimes expand the number of cases they would look at. So it's very important to safety that that team collaboration happens.

Senator BLUMENTHAL. And the team's report then goes to someone at CMS, or——

Ms. BONNER. It first goes back to the state survey agency, and I know Barbara Cass is here today. She is the director of the agency in Connecticut. So it would go back to the agency, and some managers would review it, and that's where the enforcement piece comes in, and I'm glad you mentioned that because we really try to have enforcement be consistent and credible across states and across the regions.

So the surveyors bring back what they saw and they discuss it with their managers. If there's still a question, then sometimes it gets referred to the regional offices, and then ultimately to the central office where we are if it's a policy question or a particularly complex case, which they very often are.

Senator BLUMENTHAL. Is it always a state team, or does it have state representation for these 5,000 site visits, which is a lot of visits?

Ms. BONNER. So we contract with every state, and every state does have a survey agency. And then the Federal surveyors are required, under the statute, to go in and do a sample as an oversight, as a quality assurance, if you will, measure. So the Federal regions will send in surveyors to do a 5 percent sample, and they go in a few weeks after the state surveyors and they repeat the survey to see if the findings are the same, if they determine any problems, any areas for retraining with the state.

And there's also an observational survey which is done. So that's where the Federal surveyors go with the state surveyors and actually see them interacting. How do they do the interviews? How do they do the observations? So that serves to really do just-in-time teaching with those surveyors, whereas with the comparative, there's a little bit more of how is the state survey agency doing overall and are there any issues. So it's our own quality improvement.

I would like to mention that CMS has been working for the last 7 to 10 years on a computer-assisted, data-driven model called the Quality Indicator Survey. So in about half of our states now, the surveyors have laptops that they take with them. So if they're interviewing a physician or they're interviewing a resident, they're entering data. The algorithms in the computer help to drive the surveyors to the areas that may be the most problematic and target that so the surveys can be more efficient and effective.

So this new computer system also generates reports. So if Barbara, who is here in a state where they do the quality indicator survey, wanted to know information about one of her survey teams or one of her surveyors—are they citing enough, are they an outlier—with this new program, we can do it. We were not able to do it nearly as well with the traditional survey.

So this program really needs continued development, but we've had several years now of study, and we're learning more about it all the time. We think it's extremely valuable in improving the survey process.

Senator BLUMENTHAL. Who makes the enforcement judgments based on the data that you collect through the survey? Is that done in Washington, or is it done at the state level?

Ms. BONNER. It's done at the state level. When there are the most egregious deficiencies cited, immediate jeopardy and serious harm, very often those will go to the regional offices for discussion. And then, again, the regional office, because they are overseeing several states, four or five states, can really try to make sure that those decisions are consistent. There is a grid that is used for things like civil money penalties and what we call scope and severity, how many people were affected and how severe was this problem.

So we continue to try to make those systems more reliable and implemented more reliably throughout all the states and the regions.

Senator BLUMENTHAL. If there are problems indicated at a particular nursing home, do you accelerate the re-review or the re-survey, the visits in that case?

Ms. BONNER. That definitely can happen. Also, if it's particularly—if it continues to happen in a facility, that will probably drive the data to have that facility on a list for potentially getting into the special focus facility program that I mentioned. So either the surveyors can certainly make the decision to go back sooner.

We also work very closely with the ombudsman, and the ombudsman can go into the facility quite often, and that's another set of eyes and ears. So we have really stepped up our partnership with the ombudsman program because with safety, the more sets of eyes that you have on the problem, the better.

So the ombudsman can go in. The state survey agency absolutely can go back in sooner, and they do that when there's the most egregious situation. They sometimes will not leave the facility if they really believe that people are at risk. The surveyors will call their managers and say that they want to stay there until the situation is resolved.

Senator BLUMENTHAL. And what is the most serious enforcement efforts that you can take, and has the level of enforcement increased in severity and frequency?

Ms. BONNER. The most significant enforcement remedy that we have is termination from the Medicare and Medicaid program. We also have civil money penalties. So those are fines, and we can give those on either a per-day or per-instance basis. So we can fine up to a certain amount per day for the most serious infractions. We can also say that there is a denial of payment for new admissions, and sometimes that's even more effective with facilities because if you are not going to be able to be paid by Medicare and Medicaid for any new admissions, it means you're not going to take any new admissions in most cases.

Senator BLUMENTHAL. And how often have you used each of those remedies?

Ms. BONNER. We have some data on that, and I don't have those numbers but I can work with you and your staff to let you know what those are.

Senator BLUMENTHAL. That would be helpful, if you could.

Ms. BONNER. Absolutely.

Senator BLUMENTHAL. You know, I imagine the argument for the push-back given to you is if you deprive us of resources, it's just going to diminish the level of care. As attorney general, I found that argument given frequently when funding cutoffs or reductions in funding were suggested. You must find it as well.

Ms. BONNER. Right, and also we have a very clear role in survey and certification, which is enforcement. We have regulations and requirements for participation, and that's what we do. But that doesn't prevent us from partnering with and networking with the quality improvement organizations, the culture change coalitions and other entities, even the professional associations, because they can do good quality improvement work that will deter. You know, if they build better systems, the enforcement, if it's effective, will promote nursing homes to want to do more quality improvement work, and those other agencies can do that with them.

Senator BLUMENTHAL. You know, you have talked about in your testimony various areas, including consumer engagement and four others that are very, very important, including enforcement. I wonder if you feel that there ought to be more authority, legislative authority from the Congress, to strengthen your ability either in enforcement or consumer engagement or any of those other areas that you mentioned in your testimony.

Ms. BONNER. I think that in the nursing home reform law, there is quite a bit of authority. I think it is a combination of using that authority effectively, and one of the most important things that we can do to be able to do that is to have Congress support the President's budget for survey and certification. That appropriation allows us to do the training and implementation and use experts such as you have assembled here today, and so forth.

But it's really extremely important that Congress supports the President's budget in 2013 for survey and certification.

Senator BLUMENTHAL. Well, I'm glad that you made that point. I should also say, because I've neglected it, that the record of this hearing is going to be made available to all of my colleagues on the Special Committee on Aging, and I hope that they will be advocates for the resources that the President is planning to request, because my guess is—more than a guess—my feeling is that those resources may not be completely adequate even themselves, knowing how the process works, and I'm not going to ask you to comment on that point. But I know that a lot of my colleagues share that feeling.

I want to focus on one area in particular, and I will take up your invitation to follow up afterwards on some of these other points. Anti-psychotic drugs, how are we doing in that area? Obviously, they've been a problem. They still are a very severe problem in many nursing homes, over-use of that kind of medication. How are Connecticut and the rest of the country doing in trying to combat misuse of anti-psychotic drugs?

Ms. BONNER. Well, we're fortunate right now that we have a new initiative, the CMS National Partnership, to reduce anti-psychotic use and improve dementia care. And through this initiative, we've been able to work with people in all the states, and one of the things that CMS has been doing is contacting state by state anyone who is interested in this area and anyone who is working on it.

So in Connecticut, you're very fortunate. You have some people at Yale University—Dr. Mary Tinetti, Dr. Elsa Weickers and others, as well as Qualidyne, the quality improvement organization here. All of these are organizations and individuals who have done specific work in this area.

So we've been reaching out to all of the states to find out who is already doing work in this area so we can learn from the best practices. We have identified at least 150 nursing homes in this country that have reduced anti-psychotic use or completely eliminated it, again over a period of years. It's really changing culture, and I know you're going to hear more about safety culture from the other panelists. But changing the culture in a nursing home from one where people reach for a medication when someone has a behavior like yelling or wandering or kicking or anything like that, as opposed to a person-centered approach, really changing that culture takes some time.

But we are now aligned with all of these different agencies throughout HHS. We're working with AHRQ that has a number of programs I know people are aware of for prescriber education, and we have SAMHSA and HRSA and other agencies that are also working in this area.

So again, on these state calls, we've been impressed that there is some work. There is a tremendous amount of work left to do. The public reporting we believe is going to be very helpful. We've been hearing from people around the country that they want the data. So Connecticut wants to know what their rate of use is so they know what kind of improvements they need to make.

But the 15 percent reduction is a national number. So some states may have a lot farther that they can go to be able to reduce anti-psychotics, and other states are already doing a better job. So we're sharing that information back to the states, working with the state agencies, regional offices, QIOs, individual researchers, and this really resonates with people, there's no question. We've had folks who are nursing home residents speak with us. We've had family members come and be part of the precedents with CMS in Baltimore. So people are really coming together around this initiative, and we have a lot left to do.

Senator BLUMENTHAL. I know that you're working on it, and yet I was struck by some of the statistics in your testimony, an increase of 12.6 percent to 14 percent of the facilities with these kinds of problems. And 19.2 percent, I think, in 2011 and 2012 two out of five cognitive impairment and behavioral, or I should say individuals who experienced cognitive impairment and behavioral problems received anti-psychotic drugs without any diagnosis of psychotic conditions, and those are very recent numbers, I gather, from your testimony. So there is really a need to address this issue, in my view, much more aggressively, and I take it from your testimony you agree.

Ms. BONNER. Absolutely, and I didn't mention what we're doing on the surveyor side. So the survey guidance was updated in 2006–2007, but as you know, clinical practice changes very quickly, so we are looking at that again. We have some experts who are pharmacists from across the country. By focusing the surveyors on this on every survey, we've said to the surveyors we expect that on every single survey, whether you think this is a problem in a particular nursing home or not, that you will be asking the nursing home administrator and the director of nurses what are you doing to reduce anti-psychotic use in this nursing home, how do you approach it.

By doing that, the surveyors will get a sense very quickly of whether or not they are approaching dementia care with non-pharmacologic approaches, individualized care. Does staff take the time to get to know a resident? Do they figure out what works for an individual and pass it along to others on other shifts, and are the direct care workers really involved? Because historically, again, the issue is we haven't considered safety culture, and so we haven't made sure that nursing assistants who know the residents best are at the care planning meetings, and that families are involved in care planning meetings. They get invited, but is there a real effort being made to involve them, particularly when someone has de-

mentia and has these behaviors? Does someone say, you know, tell me about your father?

If you were the patient, I would say to your family, tell me about what was Senator Blumenthal most proud of? What did he write about in the Yale Law Journal? And maybe they would bring in some articles that you worked on or some cases. So I would learn enough about you that you would start to trust me as a caregiver and we would have a relationship. So on the days that you were feeling anxious or upset about something, I would know something to talk about with you that even if you didn't remember what you had for lunch that day, you would probably remember some of those things that are really hard wired.

Dementia care is like cracking a code sometimes. It's like really getting to that one thing that will still work with someone even when their brain is very diseased, and that's what the facilities that have been successful have been able to do, and they've really involved the direct care workers and the rest of the team.

Senator BLUMENTHAL. Well, I would be interested in that list of 150, and especially if any of them are in Connecticut. Maybe we can use them as models for what should be done elsewhere. I agree that part of it is culture, but enforcement against abuse or misuse also sends a signal about the importance of changing culture and changing standards.

Preventable falls, maybe you could comment a little bit about the work that's being done there, which I gather is not unrelated to the overuse or misuse of anti-psychotic drugs.

Ms. BONNER. Right. When people are on high doses of anti-psychotic drugs, obviously that's one of the many factors in falls. So falls is a really complicated problem because it's multi-factorial. There can be issues in the environment that lead to falls. There can be medications, disease processes, things like Parkinson's and diseases that affect balance, vision, activities, all manner of things. So there are many, many fall risk factors, and falls are one of the top deficiencies that are cited by surveyors.

One of the things that we're doing that we think will be important is through our public reporting and increased transparency on Nursing Home Compare, we're going to be posting this summer a new quality indicator, a quality measure. That will be the percentage of residents who have sustained a fall with a serious injury. We're not necessarily trying to prevent everyone from every single fall. Some falls are not injurious, and we don't want to tie people down, as we did in the past.

So this new measure of serious or injurious falls will again allow a facility to look at their own data and use a data-driven system to improve quality, and this is also what we're teaching in the Quality Assurance and Performance Improvement initiative. So through quality assurance performance improvement we're developing a set of tools in technical assistance that the QIOs can use, the professional associations can use, and they will be available on a CMS website in the next several months. So facilities will be able to see, oh, here are some tools that we can use to reduce the risk of falls in our facility, and then along with the public reporting, it helps us because consumers go on Nursing Home Compare and

they see what's on the website. So if they're considering a nursing home, now they have information.

So they can go to the nursing home administrator and say, you know, I went on Nursing Home Compare and I saw that your nursing home had a high rate of falls. Can you tell me about that? And there might be an explanation in terms of the types of residents that that nursing home takes, but it's a very good question to ask a nursing home administrator. So it gets that dialogue going.

So we're really trying to get consumers more involved, nursing home residents more involved. I know Brian Capshaw is here today. He's a nursing home resident in Connecticut. He's done some work with us, and he's a good student of the regulations and helps remind us about things very often. But in terms of falls prevention, consumers being really well educated and asking good questions is something that CMS very much is in favor of.

Senator BLUMENTHAL. And I gather the Quality Assurance and Performance Improvement program is aimed at all of these problems. It is also aimed at something that I think is also very important: establishing a partnership with hospitals so as to reduce premature discharges or readmissions that are so expensive to CMS and to states.

Ms. BONNER. Right. Almost any clinical issue involves some sort of care across that transition, whether it's a pressure ulcer and someone is left on a stretcher for too long and it gets worse, or an anti-psychotic that was prescribed in the hospital and then is no longer needed but the information doesn't get transferred, so the person is just continued on the anti-psychotic in the nursing home, and all of these transfers back and forth.

So absolutely, the QAPI program requires a plan on the part of the skilled nursing facility, and it's got to be systemic. It's got to address problems across every component of the skilled nursing facility. It's not just about nursing. It's the maintenance department and the housekeeping department and the business office, across all of those areas, and it's also got to make sure that the nursing home knows how to use data and is managing with data, that leadership is involved, and that projects—you know, small tests of change. So testing out a project to see what—let's take fall prevention.

They might say, well, we've got a problem with falls. We've looked at our data. Let's try one thing with just a few of our staff on one of our units and see if we can reduce the falls on that unit through some interventions. Maybe regular pharmacy rounds of the medications would be an example that a number of facilities have tried. And then they would look back and see if there was improvement, and if there was, then they might expand it to the rest of the facility.

But those systemic kinds of approaches in their plan is what the QAPI program is about.

Senator BLUMENTHAL. Among the nursing homes that have been particularly active on anti-psychotic drugs or on preventable falls, can you give us an idea whether any are in Connecticut? That is, the good guys, so to speak, who have done really pioneering work on these issues.

Ms. BONNER. There are definitely a number of homes in Connecticut that have done pioneering work in a number of areas, not only anti-psychotics and fall reduction. Again, with Dr. Tinetti at Yale, and Dr. Baker also, and those programs around Warfarin use. Warfarin is an anti-coagulant that leads to bleeding and is a very high-risk drug. It's very often associated with morbidity and mortality, and there are some programs, some pilot programs in Connecticut that have looked at how nurses in nursing homes monitor a high-risk drug like Warfarin, and the principles were the same as monitoring similar, an anti-psychotic high-risk drug as well. So there has definitely been some very good work in Connecticut.

Senator BLUMENTHAL. Well, I'd like you to give me a list of them because I'm going to go visit them.

Ms. BONNER. I'm glad you want to go visit the good ones.

Senator BLUMENTHAL. Well, I'm going to go visit some of the bad ones as well.

But I really want to thank you for your being here today. It really means a lot, and we have a lot of areas that I would like to pursue with you. I think you may know my staff, Rachel Pryor, who deserves credit for helping to put this hearing together, and when we're all back in Washington I'd like to make a point of getting together again and getting some of that additional information.

We could spend a lot more time here but we have another panel afterward, and they are busy. I'm sure you have places to go as well, and I just can't thank you enough for the good work that you're doing, and your colleagues at CMS as well, in this very difficult and challenging area. It is so critically important not only for saving dollars, which will be a priority going forward as the Affordable Care Act is implemented, but also for stopping the kinds of patient safety violations that are so negatively impactful on people's lives.

So thank you for your great work, and thank you for being here.

Ms. BONNER. Thank you. We look forward to those further meetings.

Senator BLUMENTHAL. Sure. Thank you, Director Bonner.

[Applause.]

Senator BLUMENTHAL. I'm going to ask our next panel to come forward.

While they're doing that, I would like to thank other public officials who are here today. I said hello earlier to our Commissioner of Public Health who is here.

Jewel, if you could please stand up? Thank you so much for being here.

[Applause.]

Dr. MULLEN. If I could just note that Margaret Hath, the Director——

Senator BLUMENTHAL. Any of your staff you'd like to introduce, please stand up.

Dr. MULLEN. They are also going to go out and survey, if you would like to join them.

Senator BLUMENTHAL. Okay. Vicki Veltri, who is the health care advocate, I saw her earlier. Thank you for being here.

[Applause.]

And I think I saw Nancy Shaffer, who is the state ombudsman. Thank you for being here.

[Applause.]

Thank you. And I also saw Jeannette DeJesus, who is special advisor to the governor, Governor Malloy. I know he's very interested in this issue.

Are you still with us, Jeannette?

[No response.]

Maybe not.

But thank you all for being here, and I introduced before Edith Prague, who is still with us.

For the next round, and if you could please come forward, we may need to get some chairs for the members of the panel.

We are, by the way, distributing cards to the audience so that you can ask questions of this panel. And what we may have to do—I'm not sure how the microphone will work, but we're going to begin with Jean Rexford, and then as we go from one panel member to another, we can have you take a seat in front of the microphone.

We're going to begin with Jean Rexford, who is a long-time friend and partner in these efforts of mine, and I want to thank her for the great work that she's done in this area. She founded the Connecticut Center for Patient Safety in 2004 and currently serves as its executive director. Her organization works to promote consumer involvement in patient safety efforts. She was previously chair of the Connecticut Health Foundation, and she has represented consumers on the National Committee for Quality Assurance and the National Quality Forum.

Jean, do you want to begin?

STATEMENT OF JEAN REXFORD, EXECUTIVE DIRECTOR, CONNECTICUT CENTER FOR PATIENT SAFETY, REDDING, CT

Ms. REXFORD. Good afternoon, Senator Blumenthal, and thank you for the opportunity to provide testimony today about patient safety and for bringing attention to this serious public health issue.

According to the Inspector General's November 2010 study, it can be estimated that there were 950 Medicare beneficiaries in our own state that died in our hospitals, and you can probably add another 22,000 people who got an infection from a facility that same year.

Behind each statistic there is a name, a family, a story of sorrow. For some, it's medical bankruptcy. For others, it is unemployment. But for all patients harmed by the health care system, there is a physical and emotional pain, a profound broken trust and disbelief that while being treated, they had been harmed by preventable medical errors.

The Connecticut Center for Patient Safety was formed in 2004 to be the voice of the consumer patient. We are determined not to be forgotten collateral damage in a terribly broken health care system. Today we are joined by other advocacy groups in the national patient safety movement. Loosely organized through Consumer's Union Safe Patient Project, we work together to promote patient safety, improve quality, and protect patients' rights.

In Connecticut, we are working with another patient-focused advocacy group called Jump Start. We are trying to shine a spotlight

on the need to put the patient first and foremost in this vast medical-industrial complex and the regulatory agencies that have in the past not always put the patient first.

We began our work with hospital infections. When I learned in 2005 that there were just two infections reported across 31 hospitals in Connecticut, I knew that it was a good issue to tackle. We were told by hospital executives with whom we spoke that most infections were expected, which revealed to me a fundamental gap between consumer and medical facility perspectives. I can assure you that no health care consumer expects to visit a licensed medical facility and acquire a deadly infection as a result of receiving care. It was not difficult to amass stories of patients and families and what had happened to them when they had acquired an infection. Keith lost his job. Mary will never walk again after a hip replacement.

We brought these stories to our legislature, and legislators added their own. Twenty-six states now have legislation requiring public reporting of hospital-acquired infections, and the Federal Government has paid attention. There is an impressive nationwide effort to begin to address infections and needless suffering and costs. But think of the individuals who have died and their family's loss because medical facilities were slow to react without legislative intervention.

We have learned over the years that legislation has limitations. The health care consumer will never get all that we want or deserve. There is absolutely no road map for the consumer patient safety movement, and only meager funding for our advocates. When funding is awarded for patient safety improvements in the clinical setting, there is never a requirement for consumer representation on medical facility commissions, panels, and workgroups studying patient safety, innovation and quality improvement. Most funded endeavors exclude patient voices altogether.

While we have worked hard to collaborate with hospitals to get a seat at the table to solve the patient safety epidemic, we concurrently faced obstruction by the industry's powerful and well-funded lobbyists serving profit motives first. We realize we had to think more creatively and decided that nurses can make an enormous difference in the quality of care in keeping patients safe. So we started an outreach program to nursing schools. Collaborating directly with providers instead of institutions seemed a far more positive way to work.

Our nursing education program has been successful and continues to grow. Some doors have now opened, and we regularly participate in state and national efforts. However, there is much work to be done to bring awareness to an issue that for too long has been accepted by the medical community, overlooked by regulators, unknown to the vast majority of the general public and unsuspecting patients, and out of the realm of consumer protection.

Without transparency and accountability, patients will continue to be harmed by medical facilities that tolerate errors at a rate unheard of in any other safety-sensitive industry. We are eager to work with medical facilities and the health care system and have just recently begun collaborating with innovators that welcome our

participation. Testimony provided later today will provide an example of islands of excellence that have begun to take shape and make progress. But why aren't these islands the norm instead of the exception?

Nineteen months ago the Federal Government launched the Partnership for Patients. It was an important initiative for health care providers, but it wasn't with patients. It was for patients. After nearly two years, we were finally contacted, advocates across the country, and invited to Washington. The next week after we were excited about showing up, we were told not to come. There was no money. There was no money for the patients, for the advocates. We were, sadly, an afterthought.

Patients and patient safety must be a reflex. Only when we become an equal partner will we begin to see safe, patient-centered care.

Thank you, Senator Blumenthal, for your never-ending commitment to ensure that patients and consumer voices are heard.

Senator BLUMENTHAL. Thank you.

[Applause.]

I am going to ask each of the witnesses in order just a couple of questions, and then we'll take questions from the audience.

Jean, thank you very, very much. You know, I remember last night reading your reference to a patient safety epidemic. Do you think that's an accurate description of the extent and severity of the problem?

Ms. REXFORD. Absolutely. In fact, this morning on the news there was a helicopter where four people died. Dr. Lucien Leaf talks about the jumbo jet of Americans that die on a daily basis from failures within our health care delivery system. These are huge numbers. And so it's not only the toll of the suffering, but it is the cost to the industry.

I have been frustrated in that we're always talking about access, we've got to have access, and I believe that. But we need to talk about what we are accessing. We want to provide safe, reliable care. It's the only—you know, every once in a while they'll say we provide experience-based medicine, and I'm thinking, we weren't doing that before? It is of concern that the patient isn't always put first.

Senator BLUMENTHAL. And what has been the response since you were invited to Washington? Have you found greater receptivity since then?

Ms. REXFORD. Well, I think people are really trying. The FDA recently asked consumers to come and spend a day at the FDA to begin communication. There were 200 people in the room. I would guess I was one of three consumers that was non-conflicted, and that has been the challenge, to find people that don't have financial ties to the industries that make up health care. Many of the other consumers were representing disease groups, whether it was Parkinson's or AIDS, all of which have heavy funding from the pharmaceutical industry.

So the non-conflicted voice is of critical importance. When I do serve on national panels, I am always thanked because I am able to say what providers really want to say, but they can't.

Senator BLUMENTHAL. Thank you very much, and we'll be coming back to you.

I'm going to invite the next panelist, Dr. David Blumenthal, who is Samuel O. Thier Professor of Medicine and Professor of Health Policy at Massachusetts General Hospital and Partners Health System and the Harvard Medical School. He serves as Chief Health Information and Innovation Officer for Partners Health System in Boston. From 2009 to 2011, he served as National Coordinator for Health Information Technology under the President of the United States, Barack Obama, and in that role he was charged with building an interoperable private and secure nationwide health system supporting widespread use of health information technology to improve patient outcomes.

There's more that I could say, but I am a somewhat conflicted observer.

[Laughter.]

To use the word that Jean Rexford did.

Thank you for being here, Dr. Blumenthal.

STATEMENT OF DAVID BLUMENTHAL, CHIEF HEALTH INFORMATION AND INNOVATION OFFICER, PARTNERS HEALTHCARE SYSTEM, BOSTON, MA

Dr. BLUMENTHAL. Well, Senator Blumenthal——

[Laughter.]

It's a pleasure for me to be here. This is a unique opportunity for me to testify before you in your home state and bring you greetings from the neighboring State of Massachusetts.

I'm going to talk about patient safety from a particular point of view, and that is from the point of view of one of the important pillars of patient safety, the availability of accurate and timely health information. We need to supply our key decision-makers in health care with the best possible information they can have at the time they need it, accurate information. Inaccurate information is an important cause of safety problems. Up-to-date scientific information, when it is lacking, is another important cause of safety problems.

This vital lifeblood of patient care and of safety, good information is one of the most critical resources that clinicians have in their care of patients on a day-to-day basis. The best circulatory system for that lifeblood in the 21st century is electronic information systems. Virtually every blue-ribbon panel and every expert that has looked at patient safety has enumerated a long list of things that we need to do, and invariably one of them is to improve information through better information systems using modern technologies, which are almost inevitably electronic.

So, this apparently very complicated topic of information technology is actually very simple. It's about empowering people to do the right thing by enabling them to know what the right thing to do is.

So, we've made a lot of progress on that topic since the Obama Administration came into office and since the Congress passed the Health Information Technology for Economic and Clinical Health Act (HITECH), which you mentioned in your opening remarks. This 2009 piece of legislation, which was part of the stimulus bill passed at that time, put aside many billions of dollars to reward

physicians, hospitals, and other caretakers for becoming meaningful users of electronic health records, which also have to be certified by the Federal Government.

Since that law was passed, very dramatic changes have occurred. The proportion of American physicians and hospitals with electronic health records has doubled. The numbers of meaningful users of electronic health records, both doctors and hospitals, is now approaching 100,000. The Federal Government has spent over $5 billion in incentive payments through the Medicare and Medicaid programs to reward them as stipulated by law.

So, we are definitely on a new trajectory, but more could be done. Specifically on the topic of this hearing and the topic of your committee, the Special Committee on Aging, there is one particular oversight that needs to be corrected under the HITECH Act, and that is that the HITECH Act does not support long-term care providers, home health providers, or rehabilitation facilities for the adoption and meaningful use of electronic health records.

This is not a wise choice. We need to do better. Of course, covering the full continuum of care is essential, and the information that's necessary to care for patients in long-term care, home care, rehabilitation, and other areas outside the acute care setting is every bit as important as in the acute care setting.

This is especially true for the 5 percent of Americans who account for 50 percent of our spending, patients with multiple chronic conditions, with chronic illnesses, the kinds of patients who one finds among the elderly and in long-term care facilities. For these patients, coordination of care is especially important to avoid safety problems; knowing what patients have received in the way of care in the past, knowing what drugs they're on, knowing what their allergies are. All of this information needs to be part of the care that's provided in long-term care settings, as well as in acute care settings.

The HITECH Act didn't cover those other facilities I think in part because it needed to start somewhere. It needed to set bounds around the level of expenditure. But as we plan for the future, it's clearly the case that the umbrella of the law has to extend to include those kinds of caretakers and those kinds of facilities as well.

As the law is implemented, there's another area where I think that Congress needs to be attentive and careful, and that has to do with the level of performance that we demand of users of these modern information systems. There are two basic, important things that information systems do. The electronic health record itself is not a powerful tool. It's just a repository for information. The power of these tools derives from two uses of the information. One is to exchange it, to enable the information to follow patients, to move wherever the patient moves; and the other is to use it to make clinicians smarter and caretakers smarter.

The latter is done through embedded algorithms, reasoning logic that takes the best information that is available to medical science, as well as information about patients, and wraps it up in a way that presents it to clinicians in a way that they can use most effectively.

Health information exchange and clinical decision support are the waves of the future, and they are both incorporated into the

meaningful use framework. The meaningful use framework encourages the use of these techniques but they are demanding, more expensive, and they require things of the profession and the health care institutions that are not straightforward. As they come into effect, especially as the Center for Medicare and Medicaid Services and the Office of the National Coordinator promulgate increasingly demanding regulations for compliance with meaningful use, I fully expect that there will be efforts by my colleagues in the health care industry to postpone, mitigate, and reduce the demands associated with the meaningful use framework. I hope the Congress will stand firm in supporting the Administration as it tries to push the frontier on making good use of information for improving patient care, for improving quality of care, for improving safety and reducing the cost of care.

The last point I would make, following a consumer representative I feel I have to make, is that one of the things that health care consumers do care a lot about is the privacy and security of information that's in medical records. They care about it in the non-health care world, in their finances and in the personal choices that they make on websites and over the Internet. But there's something special about health care.

So, I think that the Congress needs to reexamine, and the Administration needs to reexamine the current privacy and security framework, because it is not currently adequate to provide the security and enable the trust that we need to make sure that patients and their families are trusting of and fully cooperating with the collection and distribution of information using electronic technologies.

So with those comments, Senator Blumenthal, I will conclude my remarks. I'd be happy to take a few questions.

Senator BLUMENTHAL. I promise only a very few.

Dr. BLUMENTHAL. None of them personal.

Senator BLUMENTHAL. In your written testimony—by the way, I'm going to ask that all of the written testimony be made a part of the record. I know that the witnesses understandably shortened what they had to say, and without objection I'm going to ask that it all be made a part of the record, and we'll distribute it to my colleagues.

You mentioned in your written testimony the radiology order entry as an example of how IT can save the system from errors or make for better and more effective treatment. That's just one example. Maybe you could just describe that.

Dr. BLUMENTHAL. Sure, sure. So this is a story that comes from my personal experience, 35 years as a primary care physician, and that I told frequently when I was working in the Federal Government. At my home institution at Massachusetts General Hospital, where I practiced for many years, we had a fairly advanced information system, and one of the things that we had was a form of clinical decision support. I mentioned it in my remarks, a way of making clinicians smarter.

What this system did was, it was called radiology order entry, required that you enter some information about the patient in support of ordering a high-cost imaging study, a magnetic resonance image study or a computerized CAT scan study of the head or the

chest or the abdomen, whatever the body part might be. And after you'd entered this information electronically, it would then do two things.

First, it would compare your test ordering and the patient's information to the guidelines of the American College of Radiology. This it did in real time. So you would get feedback in milliseconds on whether your decision conformed to the recommendation of the nation's best thinkers about ordering tests.

The other thing it did—both these systems, by the way, were home grown—is it looked back through the patient record, and if the same test or a similar test had been ordered within three months, it would essentially say are you sure you want to do this, because either you or somebody else had just ordered this test, and you might be able to get the information you need without doing this high-cost test.

And we found, I found personally and I know that many of my colleagues found, that either they weren't aware that something had been ordered or their logic may not have been in accord with expert opinion, and often this meant changing a test to order a different one, either adding something to it or taking something away. Sometimes it meant canceling the test altogether because a similar test had been done and the information was available.

So what this did is it actually reduced the collective costs across the health system, the collective amount of high-cost images that were ordered over time. There was a very dramatic reduction in the rate of increase in those tests, and I often think of this as kind of health policy nirvana. What it did was it got physicians to change their behavior in a way that made the care higher in quality, reduced the cost of care, prevented unnecessary radiation exposure for patients, and prevented them from being inconvenienced by the need to come back to get a test. Often we would end up sending patients to outlying facilities because at Mass General our facilities were so busy. So, it saved all that inconvenience, and it did it with no coercion, no financial incentives. It just made doctors better at what they wanted to do, better professionals.

So that's sort of the power, I think, of information at the right time and the right place. If you'd given that information a half-hour later, it wouldn't have been worth anything. But because it was present at the time the test was ordered, it made a huge difference. We have almost unlimited opportunities to do that using information technology.

Senator BLUMENTHAL. And it saved money.

Dr. BLUMENTHAL. It saved test ordering, which saved money.

Senator BLUMENTHAL. You mentioned that 5 percent of the individuals who receive health care are responsible for 50 percent of the spending. Is that an inevitable proportion, or are there steps that we can take either through long-term care efficiencies, nursing homes, rehabilitation, to drive down those costs?

Dr. BLUMENTHAL. Well, we can drive down, certainly reduce the rate of increase in the cost of that 5 percent. I think it's unclear whether you can ever or would want ever to spread those costs across a larger proportion of the population. The fact is that as we age as a population, we tend to get more people with chronic illness, and they tend generally to be a minority of the population.

So I don't expect that proportion, that concentration of cost to change, but I think we could care for that group more efficiently.

Senator BLUMENTHAL. The concern that you raised about privacy and security is very much on people's minds, whether it relates to IT or simple paper records, and I've actually sponsored a measure and have a number of co-sponsors—it's been reported out of the Judiciary Committee—that would impose requirements for actual systems. Many corporations, including health care institutions, have no systems, and it provides penalties in the event that they don't, and provide a private right of action in the event that there are breaches, and other remedies in the event that there are breaches.

But I think you've rightly identified the medical care area as one where people are understandably and rightly sensitive, and I take it that you feel that there is the need for additional protection.

Dr. BLUMENTHAL. Yes. There is the need in part because though we complain in the medical profession and in the health care industry a lot about HIPAA, which has become kind of an epithet as an obstacle from different points of view, an obstacle to whatever people are setting out to get, the fact is that it was created in the pre-Internet age. It was created before the current use of information was ever imagined, before the Internet, with all its benefits and all its risks, was considered.

So there are whole groups of institutions which now are custodians of health care data—take Microsoft and Google as two—that are not at all regulated under the HIPAA provisions. There are also big gaps in HIPAA itself. It's actually quite porous and fairly easy for practitioners to exchange information, to move information around legally, and often necessarily, without getting patient consent.

So that's not to say it's the wrong thing to do, but I do think it needs, in the Internet age, to be reexamined. This will require a series of things. It requires some of these necessary changes and considerations to be done through regulation. You don't need congressional action. Some will need, though, congressional action because they are part and parcel of the regulation of information in commerce using the Internet, and that is a topic that is under active discussion right now. It's not an area of my expertise, but I do understand that you can't address the health care area in complete isolation from all the other uses of the Internet.

Senator BLUMENTHAL. Susan Davis, who will follow you, talks about patient misidentification and the potential with the same name, the same birth date, to be misidentified and confused. Is that a problem that you saw during the time that you served as national coordinator in this area?

Dr. BLUMENTHAL. It was a great concern. Of course, the less privacy you have, the easier it is to identify people. The ultimate form of identification would be some kind of national patient identifier, and I was often asked about that. If we all had to have a unique number that was incorporated into our medical records, it would be from an information standpoint very easy to avoid making errors in identifying patients. But that would run afoul of many deeply held views about what the role of government is, what it should know about people, and I don't see that as likely.

Lacking a unique number associated with everybody, we will never find a way to identify people that is absolutely perfect and secure with 100 percent accuracy. So the challenge is to identify the best technical systems that we have to identify people with an error rate that's tolerable, and educating the public about that as a risk of information systems inherently is a big challenge.

It's not reasonable absent a national identifier, and even to some degree with a national identifier, it's not reasonable to expect that we'll ever have 100 percent certainty in identifying individuals, especially with common names and without very distinguishing physical or medical problems.

Senator BLUMENTHAL. Thank you, and thank you for your testimony today.

Dr. BLUMENTHAL. My pleasure.

Senator BLUMENTHAL. I'm going to ask Susan Davis to take the microphone next. She is the CEO of St. Vincent's Medical Center and Market Leader of the Ascension Systems of Hospitals across New York, Connecticut, Florida, and Alabama. She has been at St. Vincent's since 2004, overseeing the most ambitious technology upgrade to support patient safety in the medical center's history and indeed probably in the history of our state. She has aggressively implemented systems of patient safety reforms that have resulted in one of the lowest rates of infection in the nation, and she's been appointed by the Connecticut Hospital Association to lead all Connecticut hospitals through St. Vincent's model and example. She has received local and national recognition for her commitment to patient-centered care, and I can say about her as well as others of the witnesses today that I've been very proud to work with you, Susan. Thank you for being here today.

And I might just mention that I know that many of you have other schedules. If you find after your testimony that you need to leave, we won't hold it against you. We're going to be keeping in contact with you, and obviously all of your testimony will be made part of the record.

Thank you for being here.

STATEMENT OF SUSAN DAVIS, CHIEF EXECUTIVE OFFICER, ST. VINCENT'S MEDICAL CENTER, BRIDGEPORT, CT

Ms. DAVIS. Thank you very much, Senator, and thank you for that very gracious introduction. My father would be proud.

The point that you made about my role with the Connecticut Hospital Association is perhaps one of the responsibilities that I am very proud of. We heard our consumer advocate speak about the need for hospitals taking patient safety seriously, and I'm proud to say that the Connecticut Hospital Association agrees and is working together with every hospital in the State of Connecticut to put aside our competitive issues that we have in our communities and work together to create a culture of safety by building in reliable behaviors amongst the health care workers.

Our objective is to eliminate serious safety events and make our hospitals collectively in the state, and I believe it's the only state in the country that has made this commitment to provide our patients and our communities a safer environment. And I'm pleased to say, Jean, that this initiative was developed with a consumer as

part of our planning group, so you're teaching us well. Thank you very much.

But patient safety is my passion, and what I am going to speak to today is not the issue of safety from the standpoint of serious safety events or building a culture of safety and reliability, but from the IT side.

I feel a little—is Dr. Blumenthal still here? Good.

[Laughter.]

I feel a little bit overwhelmed by his presence, but I'm going to try to give you a perspective from the health care side.

Senator BLUMENTHAL. He's much more imposing than I am.

[Laughter.]

Ms. DAVIS. Not so.

[Laughter.]

But as you know, St. Vincent's is part of Ascension Health, which is the largest Catholic health system in the country and has undergone a number of initiatives around the country to create an IT platform that will enable us to use information technology to improve the delivery of care across the continuum, because it's not just about hospitals. As we move forward with the Affordable Care Act, the exciting part of it is we're going to be looking at payment for value and also payment across the continuum. In order for us to be able to do that, we need to be able to transport information and data about the patient across that continuum.

Unfortunately, that's not the case today. The Bipartisan Policy Center in Washington, which I'm sure you're familiar with, issued a report that highlighted a number of issues that need to be addressed if we're to be successful in building an electronic infrastructure to support quality, value, and the care across the continuum.

Our delivery systems and payment reforms must promote quality and value, but they require providers to deliver care and bring important health care information about the patient to the point of care. And while the High-Tech Act has been very significant in exacerbating the adoption of electronic health records, we have two major issues that I'd like to speak to. One is the interoperability of our information systems, and the second is the unique patient identifier.

On the interoperability of our health care systems, I'd suggest that there needs to be standards and certification requirements associated with CMS' Medicare and Medicaid EHR programs, and they should be expanded at Stage 2 because we need to be required to transmit additional data across providers and in different settings, and that's not the case today. Clinical IT vendors have proprietary standards which prevent easy data exchange between systems, and frankly, those proprietary practices are barriers.

Think about the fact that the U.S. banks have figured this out long ago. Without standards, investments in HIT are minimally optimized and increases the overall cost to the health care delivery system.

The second point I'd like to raise is one that you discussed with Dr. Blumenthal, and that is the unique patient identifier. Again, the Bipartisan Policy Center issued a report titled "Challenges and Strategies for Accurately Matching Patients to Their Health Data."

In Harris County, Texas, there are 2,400 people named Maria Garcia; 231 of them have the same birth date. In that county alone, there are almost 70,000 pairs of patients who share both names and birth dates. That's not unique to Harris County, Texas or the State of Texas. That happens across this country, and patient misidentifications vary from 8 to up to 20 percent and have significant impact on medical errors.

While we need to be conscious and concerned about patient privacy, we also have to find a way to move closer. I understand that Dr. Blumenthal said that we will never have a unique patient identifier, but we have to move closer on that continuum to eliminate this problem of duplication of names and birth dates to improve the safety of the health care we provide to patients.

Hospitals have developed workarounds, but those workarounds are dependent on people. Human error occurs, and people need to be added to health care systems to do this manual work, and that only adds cost to the health care system.

There is one additional point I'd like to make in closing, and that has to do with the alignment of Federal quality measures. CMS has offered three ways for providers to begin moving to provide accountable care under its newly-created Accountable Care Organization program, Medicare Shared Savings, Pioneer ACO, and Advanced Payment Initiative. These are very, very exciting opportunities for hospitals.

One of the best parts of those three initiatives is the fact that the measures across the various payers, either Federal, state or local, are required to be consistent measures. It enables those participants in those three programs to pull data that is the same for each of those initiatives. We are really appreciative of CMS' efforts to standardize data and data measurements. However, it has to go broader than to those providers that are participating in these accountable care organizations.

The broader U.S. health care system needs to align both its payment and technology processes to assure high quality and high value. Health IT and provider adoption of EHR technologies must become an integrated component of the health care system transformation that is grounded in policy which facilitates provider access to secure patient health information.

I welcome the opportunity to serve as a continuing resource to you in your important work, and thank you for inviting me to be part of this testimony.

Senator BLUMENTHAL. Thank you, and we certainly will take advantage of your offer to be a continuing resource.

You mentioned that the effort has to be broader than the ACO, the accountable care organizations. Can you expand on that a little bit?

Ms. DAVIS. Yes. I'll take it from a local perspective. We provide measures on almost 75 indicators. Now, I'll make two points on that. First, we have got to move from process measure to outcome measures because that's the value that we provide, the outcome to the patient. Patients can still get bedsores even if we're being measured and the fact that we document turning patients every two hours. The definition of those outcomes are different when

we're reporting them to insurers, managed care companies, CMS, Joint Commission, or statewide agencies.

So what we need as providers is a consistent definition of those outcomes so that we're able to report it to everyone. We believe in transparency, but when you take those 75 measures and put three or four different definitions in there, it's just additional work and opportunities for error, and it takes us away from ensuring the outcomes that we want to deliver.

Senator BLUMENTHAL. Good point. You also mentioned—that one of your recommendations is to expand consumer engagement in electronic tools. How exactly do you think we ought to do it?

Ms. DAVIS. Well, you know, I think we're fortunate to have organizations like Jean's who really advocate for the consumer; not to say that we as providers don't also advocate for the consumer. But it's amazing to me the amount of information that's out there that consumers do not gain access to, and I think we need to start with educating consumers about the information that is available to them now to help improve their health outcomes.

But in addition to that, I think that patient portals that can be developed by hospitals, by a health system, and giving patients access to them in an easy, accessible way is one of the best ways for patients to get access to their information. But in order to do that, we need interoperability, and we need unique patient identifiers to protect the privacy of those patients that have duplicate personal patient information.

Senator BLUMENTHAL. And these ideas, I think, really go very well with the suggestion that Jean Rexford made, that we need partnerships for patients, but even more partnerships with patients so that they are involved and engaged as participants, not just the objects of what happens.

Ms. DAVIS. Absolutely. As health care providers, we sometimes think that we know what patients want. We don't. And unless the patient has a seat at the table, we're not going to move this health system along as we need to, to better meet their needs.

Senator BLUMENTHAL. Thank you.

I'm going to ask—I wish we had more time for each of our witnesses, but I know that we are limited in terms of time. I'm going to ask Ms. Henderson, CEO of Hill Health Center, Connecticut's oldest community health center, to be our next witness. Since her arrival, she has directed the rebuilding efforts of a legacy institution with a 40-year track record of innovative patient care.

I've been tremendously impressed by the great work that you've done there, and thank you so much for being here with us today.

STATEMENT OF JAMESINA HENDERSON, CHIEF EXECUTIVE OFFICER, CORNELL–SCOTT HILL HEALTH CENTER, HARTFORD, CT

Ms. HENDERSON. Thank you. Thank you so very much, and good afternoon, Senator Blumenthal. Thank you for the opportunity to contribute to your research on this most important subject.

I am Jamesina Henderson, CEO of the Cornell-Scott Hill Health Corporation, Connecticut's first federally qualified health center and one of its largest. And may I add that each federally qualified

health center is required to have 51 percent patient participation on its board of directors, so there is patient voice.

We were established in 1968 as a primary care institution, and through our 44 years of growth, expansion, and development of services in medical, dental, and behavioral health care, we have become the nation's best example of integrated care. We're not alone in arriving at this conclusion. Linda Rosenberg, the CEO of the National Council of Behavioral Health Care, who visited with us recently and is responsible for leading an association comprised of over 1,900 behavioral health care organizations nationwide, stated that in all of her experience, we are the best example of integrated care that she has ever seen.

I believe our perspective on care integration is critical to your efforts on patient safety, and I'd like to explain why.

Throughout our history of providing care to the 33,000 people who consider us their medical home each year, we have focused on delivering a quality experience, from scheduling to the reception desk to the treatment room. One of the challenges we have faced is ensuring the appropriate sharing of information between our medical, dental, and behavioral health providers. Many of our patient population receive services from all three disciplines, and as many of you know, there are many connections between mental health and physical health.

In one of our most recent efforts to tackle this problem head-on, which is what we like to do at the Cornell-Scott Hill Health Corporation, we challenged the marketplace to provide what we know is the right contributory solution to improve patient care and patient safety, a completely integrated electronic health record structurally built on a foundation of information sharing across all three care disciplines. We demanded a solution that mirrored our practice of integrated care, and only one solution provider heard our call.

I'm proud to say to this committee that the Cornell-Scott Hill Health Corporation, in partnership with General Electric, is leading the transformation of electronic health records. Our system, which is now in place at several of our 16 care sites, is likely the first in the nation to provide full integration and sharing of information across all care disciplines.

We know from experience that communication and sharing of information is critical to patient safety, continuity of care, and to an enhanced patient experience. Technology aside, there are other ways we know this to be true. And like the technology solution we are implementing, there are other collaborative and partnership solutions underway in our health care environment equally deserving of mention.

Today we have no less than three programs in place, funded through foundations and others, to provide patient navigation services to patients with specific conditions. Just last month we were awarded a grant from the Komen Foundation to provide patient navigation services to women with breast cancer. What these foundations know and are willing to put their funding behind is the true value of communication, information sharing and care management. They know that if patients diagnosed with specific condi-

tions are assisted along the path of the health care continuum, they stand a better chance of improved health outcomes.

Technology cannot do this alone. It is an important, even critical component, but the human component is needed. Patients need to know they have an advocate fighting for them, working with them to ensure their needs are going to be met. This gains increasing importance as the population in general, and our patient population specifically, ages. More complex medical conditions and treatment regimes, including medication adherence, demand greater attention.

Patient navigation is a clear success story. With it, we stand a better chance of our patients receiving the right care at the right time in the right place. Patient navigation can help us reduce non-emergency visits to emergency departments, which of course everyone knows will reduce costs throughout the health care system. What makes this a difficult solution to implement is the simple fact that patient navigation services are not a reimbursable expense from our current payer mix.

Another challenging aspect of providing this service is the lack of training and workforce development opportunities to help us transform the existing workforce into 21st century caregivers capable of coordinating care across multiple specialties and institutions while simultaneously delivering on our promise of an exceptional experience.

I'd like to make one additional point before concluding with the recommendations. All of us in the health care field understand the growing complexities in delivering quality care. With the confirmation of the Affordable Care Act, we know the future of health care is going to be different tomorrow than it is today. One area we know will not be different is the expectation of our patient, high quality and safe care from their provider. We believe the vast majority of our patients have elected to make us their medical home precisely for that reason.

A medical home is more than a label. It is an affirmation of expectation and of value. And underpinning that expectation and acceptance of a medical home is trust. The simple and powerful truth is that our patients place their trust in us, all of us in the health care field, to do what is best for them. A successful handoff or transfer of a patient and their clinical information builds trust, and when coupled with the overt acceptance of responsibility for an individual's care, then and only then have we all succeeded in transforming health care.

My recommendation to you, Senator Blumenthal, and to your colleagues on this committee and in the Senate, is to draft legislation that supports our efforts to provide seamless, accountable, and beneficial patient navigation across the health care spectrum. With it, we can improve patient safety, achieve better outcomes, and reduce costly interventions.

Once again, thank you for the opportunity to share my thoughts on this most important issue.

Senator BLUMENTHAL. Thank you. And by that recommendation, I assume you would also recommend that patient navigation be a reimbursable expense.

Ms. HENDERSON. I certainly do.

Senator BLUMENTHAL. And how would you, if you were to make that argument, or elaborate on it I should say, talk about how cost effective it will be, that the investment is worth the savings, the improved effectiveness of health care.

Ms. HENDERSON. Well, I think it's well known the cost of the improper use of emergency departments, and the reason people do that is because they are directed by the system to go to the emergency room. That structural guidance needs to change, and we need more people. As much as we applaud the electronic health record, there is nothing like an actual person helping to assist patients go to the right place and encouraging them to transfer information essential to their better health.

Senator BLUMENTHAL. And that's what's necessary to permit and foster and promote patient navigation, which is really navigating for patients in what is now all too often a maze to them.

Ms. HENDERSON. Yes.

Senator BLUMENTHAL. Seemingly a maze of fragmented, different stops along the way to health care.

Ms. HENDERSON. Absolutely, and to encourage their active participation in whatever that acute situation is, and their prevention and wellness. We expect to differentiate in the future at the Hill Health Center by focusing on prevention and wellness and active, proactive engagement of patients.

Senator BLUMENTHAL. Well, I want to thank you. First, congratulations on having a fully integrated health IT system.

Ms. HENDERSON. Thank you.

Senator BLUMENTHAL. And for your use of patient navigation, and thank you for being here today.

Ms. HENDERSON. Thank you very much.

[Applause.]

Senator BLUMENTHAL. We're going to go to Scott Ellner. Dr. Ellner is the Director of Surgical Quality and Trauma Surgery at St. Francis Medical Center. He completed a Patient Safety Leadership Fellowship with the American Hospital Association and the National Patient Safety Foundation. He is co-founder and chairman of the Connecticut Surgical Quality Collaborative, which is a statewide data-sharing framework for all Connecticut hospitals to learn from each other.

Thank you for your great work in this area, Dr. Ellner.

STATEMENT OF SCOTT ELLNER, DIRECTOR OF SURGICAL QUALITY, SAINT FRANCIS HOSPITAL AND MEDICAL CENTER, HARTFORD, CT

Dr. ELLNER. Thank you, Senator Blumenthal. It's a pleasure to be here today amongst all the esteemed luminaries on this panel, and I'm excited to testify on behalf of a surgeon's perspective on value-based health care delivery.

As a general and trauma surgeon employed at Saint Francis Hospital and Medical Center, I am honored to share with the committee our efforts to improve the value of health care delivered to our patients. Value can be equated to health outcomes for every dollar spent on health care services. This value proposition redefines the next steps which should be taken toward health care reform and which can be achieved through the full continuum of

care; simultaneously improving the experience for patients and their families, improving the overall health of populations, and reducing the per-capita costs of health care provided.

Now, Susan Davis had discussed outcomes, and my vision as a health care provider is about improving patient outcomes and moving away from studying process measures, but, looking at outcome measures, and this can be done through the careful measurement of these outcomes.

It's a well-known management axiom that if it's not measured, then it cannot be improved. Over the last five years at Saint Francis Hospital, my team has collected and reported on 30-day post-surgical complications through a risk-adjusted and transparent database. Knowing our outcomes has allowed us to realize not only how good we are, but how much better we can be. Over this time period using our data, we have implemented specific patient safety initiatives to improve our patient safety outcomes.

For example, nurse-driven protocols for early removal of in-dwelling urinary catheters resulted in a 62 percent reduction in urinary tract infection rates. Improved care bundles in the intensive care unit to prevent hospital-acquired pneumonias reduced our pneumonia rates by 33 percent. We developed an operating room team training program to effectively implement a surgical checklist to prevent safety-compromising events in the surgical setting. This resulted in a 70 percent reduction in post-operative complication rates, and I'm proud to say we were recognized by the Joint Commission for demonstrating best practice during our time out for universal protocol in the operating room.

This has a big impact on costs. Knowing our outcomes has allowed us to develop these performance improvement initiatives to prevent costly readmissions in health-care-acquired infections. In fact, two years ago in one study, we found on average that patients who developed the dangerous C–DIFF infection, which is hospital-acquired or health-care-acquired, added up to an excess cost of $54,000 to those patients' care. By obtaining better outcomes, we can identify opportunities to eliminate waste and reduce those costs.

Through our electronic health record system, our information is now streamlined so we can automate our data collection for real-time monitoring and make adjustments as needed.

I'll tell you, this morning I saw 22 patients in my office on my electronic health record. All the data was input. I wrote a letter to each of their primary care physicians and the patients received a summary of care to go home with for them to use for transfer to other physicians if they didn't have the patient portal system. So we are implementing the electronic health record to its fullest potential not only to help the patient navigate the system but also for measuring our outcomes.

But, we have to be prepared to change the culture in order to make these adjustments, and this starts with medical school training. The behaviors and actions of the doctors today come from the core curriculum in the medical schools and the residency training programs. We are, in fact, still taught 19th and 20th century management principles for human interaction. Consequently, there is a hierarchy or an authority gradient in medicine which exists today,

and at times this can be intimidating to patients. It can impede communication and collegiality among providers: be they doctors, nurses, pharmacists, or physician assistants. It's time to level this authority gradient, to remove these behaviors, to better the communication so that we can work together as a cohesive unit for the betterment of our patients.

I'm proud to say that next week at the University of Connecticut, School of Medicine, we will be teaching our first course in patient safety as part of their curriculum. We are going to be teaching the future providers in health care how to be the best advocates for their patients and how to work together as a cohesive, integrated unit.

Jean has been an important advocate for her patients, and we have reached out to her, and recently, last March at Saint Francis Hospital, we had a very successful patient safety awareness day with a goal of collaborating with our patients. We brought them in from the community and we discussed efforts on how they can safely navigate the system. It was a successful day where patients felt like they were listened to, and on the other hand we were able to hear what they had to say to help them come to the hospital and leave safely.

One other thing I just want to mention is that Hospital Compare is now looking for hospitals to present their outcomes data, and what we have done is we have participated in a new pilot, the only hospital in Connecticut to report our elderly serious outcomes after surgery.

So with that, I want to thank you for allowing me to testify today. It's been an honor.

Senator BLUMENTHAL. Thank you for being here. I feel badly——

[Applause.]

I feel badly for taking you away from those 22 patients and others that you would be seeing right now, but your contribution has been immeasurable. Quite honestly, those numbers of reductions in urinary tract infections and pneumonia and other accomplishments, measureable outcomes, are really extraordinarily impressive.

I guess my first question is: was it difficult to get support or buy-in from the nurses and the doctors and others who are in the trenches for the steps that were necessary to achieve those outcomes?

Dr. ELLNER. Well, I think that one of the challenges that you have to face anytime that you're going up against an embedded culture is to change the mindset from the way we've always done things to the way we should be doing things on behalf of patient safety.

Because I am a frontline worker, I'm there in the trenches—I was there last night operating on a patient with a small bowel obstruction—they know me. They are able to relate to me and understand that if I'm truly passionate about this then this must be important. And so I was able to develop a team of stakeholders who understand it. Some of them are here today. Then I was able to go to senior leadership, particularly our CEO, Chris Dadlez, who has been behind us 100 percent and he understands the importance of this.

I can tell you that if the leadership in your organization understands how important patient safety is, then you're going to be successful. It aligns the organization.

Senator BLUMENTHAL. Well, I know your CEO, and I'm very glad that you brought some of your stakeholders and your team here today because they really show how leadership can get results. This is not pie in the sky stuff. This is real-life steps that can be taken, can achieve results, and I think it's a very powerful story.

I guess the other question I have for you is: do you think that the teaching, the curriculum that you developed for the University of Connecticut, can be replicated and done elsewhere?

Dr. ELLNER. I believe it can. We look at the World Health Organization as a model and use some of their baseline teachings to develop the core curriculum, and the goal is to not only roll this out here at the University of Connecticut but to implement it in the nursing programs and the pharmacy schools so that it's an interactive process with all health care providers, not just the physicians.

So ultimately that is our goal. And then on a side note, what we'd like to do is make this into a 4-hour certification program for all providers, for all personnel within our hospital, so that like you have to become basic life support certified, know how to do CPR, you have to be patient-certified, patient-safety-certified.

Senator BLUMENTHAL. Patient safety certified. That would be a great qualification to spread more generally among health care providers and institutions.

Well, thank you very much.

I'm going to ask questions that have been submitted by the audience, and I guess some of them are general questions, and I'm going to ask them in exactly the way they have been written and open it to whomever would like to respond if they're not addressed to one person, and identify who has submitted them.

The first is from Ann Yedlin of New Haven, and the question is: "What role does staffing play in patient safety, and how is this being addressed? Numbers, training, empowerment." For any of you who would like to respond.

Ms. DAVIS. I'll try taking a shot at it. I think there are a lot of studies that are out there that talk about the relationship of the number of registered nurses to patient outcomes, patient satisfaction. So I think that's got to be an issue amongst all of our hospitals, within all of our hospitals, because there are data there that supports it.

But it's just not having a person. It's just not about numbers. It really is about the culture in our organizations and the behaviors that we all exhibit. We talk about in higher liability of 200 percent accountability. I'm accountable for the work that I do, but I'm also accountable for the work that Jean does in making sure that if I see her forgetting to wash her hands or not putting isolation balm on, I stop her; speaking up, creating a culture where employees, it doesn't matter what you do in the organization, whether you're the CEO or a registered nurse or a housekeeper or dietary worker. If you see a health care provider doing something that you know is wrong, like not washing their hands, or putting a mask on when you're going to put a central line in, you have to empower those

individuals to speak up, to stop the line, so to speak, and that's not about numbers. That's about culture. That's about setting the expectations within the organization.

Senator BLUMENTHAL. Thank you.

[Applause.]

Our next question—I'm asking these in the order that they were submitted—is from Maggie Ewald, who is the Long-Term Care Ombudsman. She's from Columbia, Connecticut. "How does a patient correct or change a previous erroneous diagnosis in his or her, medical record?"

[No response.]

PARTICIPANT. Well, I guess they don't.

Ms. DAVIS. No, they do. They absolutely do. Most organizations have a process for that in their policy that enables that to happen. It's not easy. I will tell you that, because a physician has written a diagnosis in a medical record, they've made that diagnosis based on scientific and qualitative data.

But there is a way in which you can contact the hospital where you believe the erroneous medical record entry is and work with the hospital and the physician to have your complaint reviewed and potential for changing the medical record.

I've seen it done, it does work, and I've seen those from the DPH standpoint understand the process. But that is generally the path that you should follow to get it done.

Senator BLUMENTHAL. Next question from Sean Jeffrey of Branford, Connecticut. "Medication reconciliation between care settings is an important source of errors and potential danger for seniors. Pharmacists are best situated to make positive changes. However, pharmacists need to be recognized by CMS as health care providers to ensure they have the ability to work across care settings to incorporate medication data across electronic records to ensure proper communication and make sure the right drug reaches the right patient at the right time. The American Society of Consultant Pharmacists looks to partner with your office and the Senate Aging Committee."

I guess that's a comment more than a question. If you wish to comment, we would welcome it.

Ms. BONNER. Thank you for that comment, and I just want to add that we are working with ASCP, the American Society of Consultant Pharmacists. Our regulations right now for the most part, as you pointed out, are really in silos. We have nursing home regulations, we have hospital regulations, we have home health regulations. One of the things that we're doing now, CMS is looking to see how do the regulations need to change now that we're looking at accountable care organizations and looking at care transitions.

The pharmacists have played a tremendous role in the anti-psychotic work that we talked about earlier, and we're very pleased that ASCP is a partner with us. So we'd be happy to work with them, and Mr. Jeffrey here in Connecticut as well.

Senator BLUMENTHAL. We have a question from Martin Spriglio of Stratford. "Will there be funding for nursing homes to put electronic health records? All others receive funding—hospitals, doctors, et cetera."

I guess I will answer that question, but I will open it to others. I certainly hope there will be funding for it, and I will support it if the President is willing to support it as well. Anyone else who wants to comment can, but I think that kind of funding for nursing homes is vitally important.

KATHY TYNAN MCKIERNAN. "What plans are underway to improve quality of care and disincentivizing quick decisions to hospitalize or re-hospitalize patients in nursing homes?"

Ms. BONNER. There are a number of initiatives that are going on, but most recently——

Senator BLUMENTHAL. Sorry about the logistics here.

Ms. BONNER. I'm sorry I have my back to you so that you can hear me. There is a recent initiative from the Federal Coordinated Care Office of Health, which is the office of the dual eligibles, people who have Medicare and Medicaid, and it is specifically a proposal. They're reviewing the people who submitted them now to look at re-hospitalization, avoidable re-hospitalization of nursing home residents. That is one of the primary outcomes, as well as, again, the use of anti-psychotic medications, and others. But that is one specific initiative where nursing homes are partnering with physicians and other groups to come in and provide primary care and work together collaboratively on primary care nursing home issues to prevent re-hospitalizations.

CMS is working with a number of partners as well. In Connecticut, there is a particular group in New Haven that was funded under the Section 3026 of the Affordable Care Act on care transitions, and that's again a group that includes skilled nursing facilities, hospitals, community-based organizations to look at unnecessary re-hospitalizations, including those of nursing home residents. So a number of the programs under the Community-Based Care Transitions section of the Affordable Care Act are looking at that as well.

Senator BLUMENTHAL. Thank you.

This is a question for Jean Rexford from Brian Capshaw, resident counsel, President of Aurora Senior Living of East Hartford. He's an executive board member of the Statewide Coalition of Presidents of Resident Counsels of Connecticut.

Is Brian still here?

Mr. CAPSHAW. Yes.

Senator BLUMENTHAL. Great. "Connecticut law requires that nursing home staffing levels result in 1.90 (second lowest in the country) total nurse and nurse's aide hours per resident per day. With this low number, nursing home resident safety is an issue, such as falls, because not enough staff is available and residents try to do things for themselves. The Federal Government leaves this up to each state. Would you support our attempt to change the Connecticut law from 1.9 to 2.3 in 2013, and 2.3 to 2.7 in 2014 in the next legislative session? The Office of Fiscal Analysis shows little cost to the state."

Ms. REXFORD. That's known as being put on the spot. It would be certainly something I would be very interested in, and our group would be very interested. We have just begun working on nursing home issues. As you know, we have focused on hospitals. But over

the last few years, we've had more and more calls about problems within the nursing homes.

Clearly, in some nursing homes it is the same complaint, whether it is medication or falls, that are repeated, and there's been a movement in California particularly that looked at staffing levels that was driven by consumers. So it would be definitely something we would consider.

Senator BLUMENTHAL. I'm going to ask Brian's next question because I think it deserves to be asked, and you can answer it or maybe talk to Brian individually since he's here. But I'd like the whole panel to hear it.

"The last three Connecticut nursing homes that were found to be negligent in causing a resident's death were fined an average of $560. Connecticut law says DPH can fine nursing homes up to $3,000. With these small fines, there is no incentive for owners to provide safe care. I've looked at recent cases from 10 other states and found the average fine to be $18,000. The Federal Government allows states to set their own monetary penalties. In the 2013 legislative session, we will be asking the Connecticut legislature to raise the maximum fine to $10,000 and the minimum fine for causing a resident's death to $2,000. Would you support our effort?"

Ms. REXFORD. We are absolutely looking into this. In fact, this past year the Connecticut legislature passed animal cruelty fines. The first time is $1,000, and it can go up to $5,000, and criminal charges can be filed. One of our members has just done a spreadsheet on what our fines are and what they are in other states, and we would be very happy to share that with your office, and I have a feeling we'll be sharing that with the legislature next year.

Senator BLUMENTHAL. And may I just say, Brian, you've asked about state law, but perhaps we can talk about changes in Federal law and obviously work with Jean and other members of the panel that may be appropriate in this area. So thank you for the question.

The next questions are first from Patricia Kellmer of Farmington, and this one is for Susan Davis. "Can you elaborate on the Connecticut Hospital Association's plans to bring culture change to Connecticut hospitals? What are your goals, and how do you intend to achieve them, especially for those hospitals not already willing to change?"

Ms. DAVIS. Sure. The Connecticut Hospital Association, through its Committee on Patient Care, Quality and Safety, has been working over the past three years to put a plan in place that will involve all the Connecticut hospitals in, first of all, making a commitment, doing education of the leadership, and bringing in a consultant from the nuclear power industry that really does work on safety to teach us about all the principles of changing behavior, because in order to change a culture, you have to start with changing behavior.

The Connecticut Hospital Association has held two boot camps in the month of June where we had CEOs, physicians, frontline staff, and medical leaders come for a two-day event. Each boot camp was two days where they learned about some of the tools that can be used and the process for helping to change the culture and create a culture of safety and high reliability, looking at serious safety

events, using tools to monitor the serious safety events and improve the outcomes.

I can speak to what we've done at St. Vincent's. We have gone through this process and we, in fact, have educated all of our hospital employees in a three-and-a-half-hour course that I taught, as well as all of our senior leaders taught to every one of our 3,500 associates about safety and reliability, and we also did the same thing for our physicians. That was taught by medical staff.

So it's a real commitment. But when you try and answer the question that you asked earlier of Scott about how you change this culture, it's easy, because you change it by touching the heart of the caregiver. Caregivers come into health care because they want to make a difference in people's lives, and when you can tell stories of people that we have harmed, unintentionally harmed, it helps the caregiver understand their role better and what they could have done differently in order to avoid that medical error.

Senator BLUMENTHAL. Our last question is from David Shapiro, and I think it's broad enough to be addressed to any of our witnesses. David Shapiro, M.D., West Hartford, "How can we truly achieve 'collaborative patient safety' if hospitals are constantly demonstrative of their competitive stance? Billboards, ads, et cetera, say 'we're the best,' but it's less than accurate."

So that one I will open to any of you. Again, I'm reading the questions, I'm not asking them, but I think all of these questions really deserve to be asked, and others, because it is the consumers, the folks who are here today, who ought to have an opportunity to be engaged and involved. So, any of you may choose to answer.

Ms. DAVIS. I'll take a shot at it first since I've had the opportunity to work through this with the Connecticut Hospital Association. What I would say to you is it's a journey, it's not an event. But to get all the hospitals in the State of Connecticut together to say we're going to put aside our differences and our competitive nature on issues and work together to share information, share data, is a huge undertaking, and it's a leap of faith, because we did have discussions where some hospitals said, well, if I'm sharing my data on my serious safety events, I don't want to see Hospital Y putting a billboard up and saying come to us because Hospital X has this many serious safety events.

We as providers have to be bigger than that. That's what I would suggest to you. We have to understand that we're not doing this for a competitive reason. We're doing it for our patients, and that's what gets us up every day to come to work.

Senator BLUMENTHAL. Dr. Ellner.

Dr. ELLNER. I think part of the culture in health care is that there's a zero sum competition right now. There's no incentive for us to display our outcomes. We get paid for quality, whether it's good or bad. So what we have to do is we have to work together with CMS or the payers to put our outcomes out there and be transparent, because that's what we're going to move toward, a more transparent outcomes reporting type of system. Unfortunately, this type of competitive or zero sum competition, as Michael Porter calls it at Harvard Business School, is not going to work five years from now. It has to be based on value, your outcomes and the amount that it costs to get those outcomes.

So part of the collaborative that we have in the state, the Surgical Quality Collaborative, we have 17 hospitals that have come together, 17 out of the 30, that are willing to share their data in a collegial framework understanding that this is about our patients. It's not about billboards. It's about improving our patient's outcomes.

Senator BLUMENTHAL. Thank you. I think that is a highly appropriate comment on which to end this hearing. If any of our witnesses have anything else they would like to add or any closing comments, I'd be happy to entertain them.

[No response.]

If not, let me just say how truly thankful I am to each of you for being here today. You have added enormously to the information available to us. I can tell you I've been in the United States Senate for about a year and a half. I haven't heard a more thoughtful or insightful panel, and I'm very, very proud that it happened here in Connecticut.

I'm very proud also that Connecticut is really at the forefront. We have some leaders here, and I think that the more we can add to this movement, the better. As Susan Davis said so well, it isn't an event. This hearing is not the end. It really is a journey, and I really want to thank all of you on the panel and others who are in leadership who have attended today for your really extraordinary work on this very, very important issue. Thank you very much.

We will keep the record open for a week so that anyone who wants to submit anything more can do so, and it will be included in the record, including, by the way, comments from others who may wish to submit them for the record.

For now, the hearing is adjourned. Thank you.

[Applause.]

[Whereupon, at 3:21 p.m., the hearing was adjourned.]

APPENDIX

STATEMENT OF

ALICE BONNER, PhD, RN

DIRECTOR OF THE DIVISION OF NURSING HOMES,

OFFICE OF CLINICAL STANDARDS AND QUALITY

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

NEXT STEPS FOR PATIENT SAFETY:

ASSURING HIGH VALUE HEALTH CARE ACROSS ALL POINTS OF CARE

BEFORE THE

UNITED STATES SENATE SPECIAL COMMITTEE ON AGING

JULY 2, 2012

U.S. Senate Special Committee on Aging
Field Hearing on "Next Steps for Patient Safety:
Assuring High Value Health Care Across All Points of Care."
July 2, 2012

Thank you, Senator Blumenthal, for the opportunity to appear today to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to improve patient safety for nursing home residents. CMS has a number of initiatives underway to improve care across settings, including by ensuring better care transitions. As director of the Director of Nursing Homes in the Survey and Certification Group in CMS' Office of Clinical Standards, I will speak specifically about patient safety in nursing homes, a single component of CMS' multiple initiatives. CMS is committed to ensuring that every Medicare and Medicaid beneficiary receives seamless, high-quality health care, both within health care settings such as nursing homes, and among health care settings during care transitions.

As you may know, more than 3 million Americans rely on services provided by nursing homes at some point during the year and 1.4 million Americans reside in the nation's 15,800 nursing homes on any given day. Those individuals, and an even larger number of their family members, friends, and relatives, must be able to count on nursing homes to provide reliable, high quality, safe care. A number of divisions within CMS work together to promote nursing home safety and quality improvement, address reimbursement issues, and enforce Medicare Conditions of Participation. The combined levers of technical assistance, payment reform, oversight, and enforcement create a powerful system that promotes safety and quality care in nursing homes.

Background

To ensure that nursing homes meet both Federal and State standards, CMS conducts initial and ongoing inspections of all facilities participating in the Medicare and Medicaid programs. The Survey and Certification process plays a critical role in ensuring basic levels of quality and safety for Medicare and Medicaid beneficiaries by monitoring nursing home compliance with Federal and State requirements. Within the Survey and Certification Group, the Division of Nursing Homes focuses on optimizing the health, safety, and quality of life for people living in nursing homes, through close coordination with other divisions. Approximately 5,000 Federal and State surveyors conduct on-site surveys of certified nursing homes on average every 12 months to assure basic

levels of quality and safety for beneficiaries. CMS has undertaken several initiatives over the past several years to improve the effectiveness of the annual nursing home surveys, as well as to improve the investigations prompted by complaints from consumers or family members about nursing homes.

However, no single approach can fully assure better nursing home care. Rather, CMS acts to combine, coordinate, and mobilize many people and techniques through a partnership approach. Survey Agencies, Ombudsmen, Quality Improvement Organizations (QIOs), and other partners are committed to the common endeavor of promoting quality and safety in nursing homes. Although these entities have different responsibilities, their distinct roles can be coordinated in a number of ways to achieve better results than can be achieved by any one agency alone. Collectively, CMS' work to enhance quality and safety in nursing homes is focused in five major areas: 1) enhancing consumer engagement; 2) strengthening survey processes, standards and enforcement; 3) promoting quality improvement; 4) creating strategic approaches through partnerships; and 5) advancing quality through innovation and demonstrations. Through coordinating and aligning these initiatives, CMS is working to spearhead ongoing improvements in quality and safety in nursing homes.

Prior to becoming the Director of Nursing Homes in the Survey and Certification Group in CMS' Office of Clinical Standards, I worked in clinical practice as a geriatric nurse practitioner for more than 20 years. As a clinician working in the field of geriatrics, I understand the key role of interdisciplinary partnerships in nursing home care, where safe, reliable care depends on close collaboration among nurses, certified nursing assistants, social workers, therapists, primary care providers, specialists, and, most importantly, the residents and families.

I have also seen first-hand the importance of balancing safety with the need for a resident in a nursing home to have a voice in his or her own care, to be autonomous, to make choices that affect their daily routines, and other basic rights. CMS encourages facilities to examine their organization's values, structures, and practices to transform traditional institutional approaches to those that are person-centered. The adoption of person-centered care principles can improve both the resident and the family's experience of care.

In the following sections, I would like to highlight some specific, recent activities that CMS has undertaken to improve quality and safety for nursing home residents in the areas of antipsychotic medication use, managing fall risk, quality assurance and performance improvement, nursing home oversight of special focus facilities, and care transitions across long-term care settings.

Addressing Inappropriate Antipsychotic Medication Use

Nursing homes play an important role in providing care for those with dementia; any discussion of how to best improve the quality of health care for Alzheimer's disease and dementia patients must necessarily involve this component of the health care delivery system. According to the Alzheimer's Association, 75 percent of people with Alzheimer's will be admitted to a nursing home by age 80.[1] While there is still much we do not understand about the causes, diagnosis, and treatment of Alzheimer's disease, there is a compelling and growing body of scientific evidence suggesting that the use of certain medications, including atypical antipsychotics, to treat the behavioral symptoms of Alzheimer's or other dementias may not be appropriate . CMS recognizes that a crucial component to improving the quality of care for beneficiaries with dementia is eliminating the inappropriate or harmful use of these medications.

In September 2006, CMS implemented substantial improvements to onsite surveys to help address concerns about antipsychotic medication use. Specifically, CMS revised interpretive guidelines for unnecessary medications, including clarifying several aspects of medication management and developing a new medication table that includes medications that are problematic for nursing home populations. These Survey and Certification guidelines are designed to assist regulators in determining whether residents receive only medications that are clinically indicated in an appropriate dose and duration, whether non-pharmacological interventions are considered, and whether gradual dose reduction is attempted when clinically appropriate. Examples of noncompliance can include excessive dosing of medication, prolonged use of antipsychotic medications without attempting dose reduction, or failure to implement behavioral interventions in an attempt to eliminate or reduce antipsychotic medication. This process is carefully balanced with the need to protect the ability of physicians to make clinical decisions on the use of atypical antipsychotic medications in people with dementia, based on the individual patient's needs.

[1] http://www.alz.org/documents_custom/2011_Facts_Figures_Fact_Sheet.pdf

Since the implementation of this guidance in December 2006, the percent of surveys with citations for unnecessary medication use has increased significantly. In the seven years prior to implementation of this change, 12.6 percent to 14.0 percent of facilities were cited for unnecessary medication use; this has grown to 18.2 percent in 2007[2] and 19.2 percent using data from the most recent facility survey (calendar years 2011 through 2012). Accurate detection is the first stage in identifying potential harm and eliminating it. CMS is working with our State partners, using this information to target educational programs and technical assistance to providers in States or regions with high citation rates for unnecessary medication use.

CMS has also worked to ensure that as part of routine onsite reviews, Survey and Certification personnel have the tools and resources necessary to effectively monitor nursing homes' compliance with these policies. For example, offsite preparation in advance of the survey includes a review of the rate of antipsychotic medication use for that facility. This enables surveyors to identify specific residents, families and staff (including physicians), to interview during the onsite survey.

Providing appropriate care to beneficiaries with dementia is more complex than simply avoiding the inappropriate use of medication. CMS also requires providers to use non-pharmacological interventions to help address behavioral or psychological issues. Possible interventions may include talking with families or previous caregivers about the person's previous coping mechanisms and ways that they used to deal with stress, using consistent staff assignment so that staff is very familiar with a resident, increasing exercise or time outdoors for the patient, managing acute and chronic pain, or planning individualized activities for patients.

In data collected from nursing homes between July and September 2010, nearly 2 in 5 (or 39.4 percent) of nursing home residents nationwide, who had cognitive impairment and behavioral problems but no diagnosis of psychosis or related conditions, received antipsychotic drugs.[3] In

[2] Federal Register, Volume 76, No. 196, October 11, 2011. Pg. 63039.
[3] CMS, MDS Quality Measure/Indicator Report, Psychotropic Drug Use, July/September 2010, Measure 10_1_HI, http://www.cms.gov/apps/mds/mds_notemp/qm_start.asp?isSubmitted=qm3&group=10&qtr=23

another study, over 17 percent had daily doses exceeding the recommended levels and over 17 percent had both inappropriate indications and high dosing.[4]

In order to address this issue, on May 30, 2012, CMS announced the CMS National Partnership to Improve Dementia Care: Rethink, Reconnect, Restore. This initiative creates a public-private partnership and a multidimensional approach to dementia care. The multidimensional strategy for this initiative includes raising public awareness, strengthening regulatory oversight, providing technical assistance and training, improving public reporting to increase transparency, and conducting research. Our goal for this national initiative is to reduce the use of antipsychotic drugs in nursing home residents by 15 percent by the end of the 2012.

CMS and industry and advocacy partners are taking several steps to achieve this goal of improved care:

- **Enhanced training**: CMS has developed Hand in Hand, a training series for nursing homes that emphasizes person-centered care, prevention of abuse, and high-quality care for residents. CMS is also providing training focused on behavioral health to state and federal surveyors;
- **Increased transparency**: CMS is making data on each nursing home's antipsychotic drug use available on Nursing Home Compare starting in July of this year, and will update this data; and
- **Alternatives to antipsychotic medication**: CMS is emphasizing non-pharmacological alternatives for nursing home residents, including potential approaches such as consistent staff assignments, increased exercise or time outdoors, monitoring and managing acute and chronic pain, and planning individualized activities.

The model for CMS' multidimensional approach to improving dementia care and reducing inappropriate antipsychotic medication use in nursing homes is based on other recent successful initiatives, such as the overall reduction in physical restraints and pressure ulcers. In those initiatives, the Office of Survey and Certification, nursing home advocates, the QIOs, and other

[4] http://www.cms.gov/apps/media/press/release.asp?Counter=4368&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date

organizations such as the Advancing Excellence in Long Term Care Collaborative worked together to significantly reduce rates of physical restraints over several years. For example, between 1991 and 2009 the percentage of long-stay nursing home residents that were physically restrained dropped from 21 percent to 4 percent. Similar results were achieved for pressure ulcer reduction as well.

Implementing Quality Assurance and Performance Improvement

CMS has undertaken an initiative to broaden quality activities in nursing homes. The provisions added by section 6102 of the Affordable Care Act (P.L. 111-148 together with P.L. 111-152) provide the opportunity for CMS to mobilize some of the best practices in nursing home quality and to identify technical assistance needs, in advance of a new quality assurance and performance improvement (QAPI) regulation implementing these provisions. The amendments under section 6102 provide that CMS shall establish and implement a QAPI program for facilities that includes development of standards related to quality assurance and performance improvement and provision of technical assistance on the development of best practices in order to meet those standards. This new provision significantly expands the level and scope of currently required activities to ensure that facilities continuously identify and correct quality deficiencies as well as promote and sustain performance improvement.

With the passing of the Affordable Care Act, CMS embarked on a mission to develop a QAPI program by December 31, 2011. During the initial phase, CMS and our contractors:

- Reviewed available tools to help manage QAPI processes in nursing homes;
- Established a Technical Expert Panel (TEP) to assist CMS contractors in developing and applying a QAPI prototype based on existing literature and practice;
- Launched a demonstration project in September 2011 in 17 nursing homes across four states to test implementation strategies and effectiveness of QAPI tools and resources;
- Engaged stakeholders in a dialogue around dissemination strategies for national rollout. These active discussions continue on a frequent basis with multiple stakeholders from around the country; and
- Appointed onsite technical assistance liaisons to visit each nursing home in the demonstration and provide them with individualized technical assistance.

The national QAPI rollout is currently underway and advancing. QAPI tools, resources, and technical assistance that are currently being tested in the demonstration will be available to all nursing homes this summer. Materials will assist nursing homes in improving their current quality programs using best practices and local learning collaboratives.

In addition to the national rollout, CMS distributed a 20-minute questionnaire to a representative sample of 4,200 randomly selected nursing homes in June 2012. We will use the results of this questionnaire to establish a baseline of QAPI practices in nursing homes, gather information on the challenges and barriers to implementing effective QAPI programs, and help shape the direction and content of the QAPI tools and resources provided by CMS to all nursing homes.

Beginning in August 2012, all stakeholders, including nursing home providers, residents, advocates, and regulators will have access to an online resource library and website that contains information about this transformative initiative. The online library provides resources and training materials that will facilitate stakeholders' understanding and implementation of QAPI. CMS plans to further these efforts with rulemaking during 2013.

Improving Care Transitions

There are significant safety risks associated with the transition of frail elders from the hospital to the nursing home. Currently, care transitions are often fragmented, with nursing home providers lacking the information that they need from hospitals to properly care for residents. This may result in medication errors or other adverse events, such as delirium and rehospitalization. Similarly, when residents are transferred from the nursing home to the emergency department (ED) for care, information that ED clinicians need from the nursing home is often lacking.

One in four residents admitted to a skilled nursing facility (SNF) is readmitted to the hospital within 30 days at a cost to Medicare of $4.3 billion per year.[5] Many factors contribute to rehospitalization, including resident factors, absent or limited communication with families, unclear goals of care or lack of advance care planning, lack of available providers in the SNF to see a sick resident, misaligned financial incentives and other factors. One study suggests that up to 45 percent of

[5] Mor V, Intrator O, Feng Z, Grabowski DC. The revolving door of rehospitalization from skilled nursing facilities. Health Affairs. 2010;29:57–64. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2826971/?report=abstract

readmissions of nursing home residents to the hospital may be inappropriate.[6] Programs to enhance nursing assessment and early identification of change in condition and to improve communication between settings are part of technical assistance provided by the QIOs to individual nursing facilities under the current QIO scope of work.

The Survey and Certification Group is currently revising guidance related to regulatory requirements for admission, discharge, and transfer of residents to better focus on nursing homes' accountability for ensuring safe and effective care transitions to and from the acute care setting. CMS is working to develop new quality measures that will track 30-day hospital readmissions among newly admitted nursing home residents.

We are also working closely with the Department of Health and Human Services (HHS) Office of Inspector General (OIG) as it begins two studies examining aspects of nursing home resident safety. First, the OIG has recently begun analyses examining the rate, preventability, and associated costs to the Medicare program of hospitalizations among nursing home residents. The OIG is also, in a separate study, examining the rate of adverse events among nursing home residents. The Division of Nursing Homes is working closely with the OIG on both of these studies to ensure that the data can inform our multiple initiatives to improve nursing home resident safety.

Managing the Risk for Falls

Each year, one out of three adults over the age of 65 falls.[7,8] Rates of falls in nursing home residents are much higher. Falls by nursing home residents may lead to hip fractures and other serious injuries, and may cause severe disability among survivors. Injuries from falls may also lead to fear of falling, increased sedentary behavior, impaired function, and lower quality of life for seniors, particularly those living in nursing homes. Falls are the leading cause of death due to unintentional injury among older adults, but many of these deaths and injuries could be prevented if multiple risk factors were addressed, including the misuse of certain medications.

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[6] Saliba D, Kingston R, Buchanan J, et al. Appropriateness of the decision to transfer nursing facility residents to the hospital. *J Am Geriatr Soc.* 2000;48:154-163.

[7] Hornbrook MC, Stevens VJ, Wingfield DJ, et al. Preventing falls among community-dwelling older persons: Results from a randomized trial. Gerontologist. 1994 Feb;34(1):16-23.

[8] Hausdorff JM, Rios DA, Edelberg HK. Gait variability and fall risk in community-living older adults: A one-year prospective study. Arch Phys Med Rehabil. 2001 Aug;82(8):1050-6.

Provider education about safe prescribing practices, including for opioid and narcotic prescriptions, may help reduce adverse reactions or falls by minimizing or eliminating the dizziness and confusion that opioids may cause, which could increase the risk of falls. In 2011, the Administration outlined an action plan to improve prescription drug safety, titled "Epidemic: Responding to America's Prescription Drug Abuse Crisis."[9] The plan calls for education of patients, providers, and community members concerning proper prescribing and risks associated with these medicines. It also calls for providers to utilize State prescription drug monitoring programs to manage medications and identify patients who may be at risk for addiction and misuse.

CMS is posting a new quality measure on Nursing Home Compare this summer that will report the percentage of falls with serious injury in nursing home residents by facility. These data will enable professional associations, culture change coalitions, QIOs and other organizations to target technical assistance and fall risk reduction programs to nursing homes with the highest fall rates.

Nursing Home Oversight Activities to Promote Safety and Quality: the Special Focus Facility Program

Between 2005 and 2010, CMS certified an average of 16,050 nursing homes each year for participation in the Medicare and/or Medicaid programs. While many nursing homes meet minimum nursing home requirements either upon the survey or within a short period thereafter, some nursing homes pass one survey, only to fail the next survey for issues identified previously and give rise to repeated cycles of serious deficiencies.

In recognition of this phenomenon, CMS created the Special Focus Facilities (SFF) program in 1998 as one of the initiatives of the Nursing Home Oversight and Improvement Program. The purpose of the SFF program was to decrease the number of persistently poor performing nursing homes by directing more attention to nursing homes with a record of poor survey performance. In January 1999, CMS instructed State Survey Agencies to conduct two standard surveys per year for each SFF instead of the one required by law. CMS also requested that State Survey Agencies submit a monthly status report listing surveys, revisit surveys, or complaint investigations of SFFs they conducted in that month.

[9] http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf

In collaboration with the States, CMS identified areas where the SFF program could be improved. Since December 2004, CMS has been working to continually improve the SFF program and increase its effectiveness by:

- ***Increasing the Number of Nursing Homes in the SFF program:*** We increased the total number of facilities by about 30 percent, with larger States having more SFFs than smaller States (instead of focusing on two nursing homes in every State);
- ***Enabling Better Selection***: Improving the data and methods by which poor performing nursing homes are identified, thereby enabling States to move on to other nursing homes on the candidate list if the original nursing homes show significant improvement;
- ***Strengthening Enforcement***: Implementing more robust enforcement for nursing homes that fail to make progress;
- ***Reducing Reporting Burden***: Removing the monthly reporting requirement for States; current requirements for surveying each SFF twice a year remain unchanged; and
- ***Building in Timeframes for Action***: Requiring that nursing homes have three standard surveys to make improvements and either graduate from the program, make significant improvement, or face termination from the Medicare program.

In fiscal year (FY) 2008, CMS made further improvements to the SFF initiative by requiring that States notify nursing homes that they are designated as a SFF and requiring that States notify other accountable parties of this designation, such as owners, governing parties, and other additional parties such as the State Ombudsman, the State Medicaid Agency, and a State's QIO.

The second improvement was posting the names of all SFF nursing homes on CMS' Nursing Home Compare website.[10] SFF's names are organized so consumers and families can distinguish between nursing homes that have significantly improved and those that have not, have graduated, or have terminated participation in the Medicare program, as well as SFF nursing homes that have recently been added to the SFF initiative. The third improvement was the inclusion of a SFF icon for those nursing homes on Nursing Home Compare website that are part of the SFF initiative.

[10] http://www.medicare.gov/NHCompare/

In FY 2011, CMS made further improvements to the SFF initiative by initiating quarterly calls to the CMS Regional Offices to discuss the status of any nursing home that continues on the SFF program for a time exceeding 24 months. CMS staff focus on enforcement remedies, quality assurance programs such as the Advancing Excellence in Long Term Care Collaborative's program conferences with ownership and management of the facility, potential assistance from the State Survey Agency and Regional Office, and enforcement recommendations such as termination from Medicare. Approximately 50 percent of the nursing homes in the SFF program significantly improve their quality of care within 24 to 30 months after being selected for the SFF initiative, while about 16 percent tend to be terminated from Medicare and Medicaid. CMS closely oversees the remaining proportion's status through the quarterly calls mentioned above. Overall, enhanced oversight of these low performing facilities has led to safer care for many nursing home residents.

Next Steps

CMS is continuing our efforts to be a driving force in health care change and a partner for our stakeholder communities in improving health care for all Americans. As a former geriatric nurse practitioner, I personally take this commitment to serve and improve our health system very seriously. In order to meet this commitment, CMS is focused on the activities highlighted above, as well as looking ahead to future care improvements.

CMS is working to improve quality and safety for nursing home residents in the areas of inappropriate antipsychotic medication use, managing fall risk, quality assurance and performance improvement, nursing home oversight of special focus facilities, and care transitions across long-term care settings. CMS plans to expand these activities by increasing the goals within the CMS National Partnership to Improve Dementia Care and Reduce Antipsychotic Drug Use in 2013 and by spreading QAPI to all nursing homes nationwide through a national rollout. We are also working to transform the nursing home survey process with continued movement towards a more effective, computer-assisted, data-driven process (such as the Quality Indicator Survey (QIS) model) for 100 percent of our nursing home surveys in the years to come.

Additionally, we are collaborating across CMS as well as HHS in order to provide the perspective on how certain programs can better meet the needs of residents in nursing homes. For example, we are working with the Center for Medicare and Medicaid Innovation and the Federal Coordinated

Health Care Office (Medicare-Medicaid Coordination Office) on the Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents. This initiative supports the Partnership for Patients' goal of reducing hospital readmission rates by 20 percent by the end of 2013. CMS is also contributing the development of the next stages of meaningful use criteria for long-term and post-acute care providers in the Electronic Health Record Incentive Program. Finally, we continue to lead the work on behalf of the HHS Action Plan for Healthcare Acquired Infections (HAIs) and collaborating with the Centers for Disease Control and Prevention on tracking State initiatives to reduce HAIs. These collaborations and future goals show CMS's commitment to continual improvements in quality and safety in nursing homes.

Conclusion

I appreciate the Committee's ongoing interest in improving the quality of care for all of our nation's citizens. Thank you for the opportunity to discuss the work CMS has been doing to improve patient safety and care in the nursing home setting.

U.S. Senate Special Committee on Aging
Congressional Field Hearing Testimony
July 2, 2012

Senator Blumenthal, thank you for the opportunity to provide testimony today about patient safety and for bringing attention to this serious public health issue. I am Jean Rexford and I am the Executive Director of the Connecticut Center for Patient Safety, a non-profit consumer advocacy organization.

According to the Inspector General November 2010 study, preventable adverse events contributed to the deaths of as many as 950 Medicare beneficiaries last year in Connecticut alone. These 950 deaths occurred in Connecticut hospitals -- this statistic does not include preventable deaths in our nursing homes or private homes, nor does it include the non-Medicare population. Another 22,000 patients acquired infections while they were treated in health care facilities and almost all of these were preventable.

Three separate recent reports in 2010 and 2011found that at least 1 in 4 patients are harmed while hospitalized. And the financial costs are staggering. Nationally, hospital acquired infections cost our economy as much as $45 billion dollars, while patient falls in hospitals and nursing homes in 2005 alone added another $34 billion in costs.

Behind each statistic there is a name, a family, a story of sorrow; for some it's medical bankruptcy, for others, it is unemployment. But for all patients harmed by the healthcare system, there is physical and emotional pain, a profound broken trust, and disbelief that while being treated they had been harmed by preventable medical errors. The CT Center for Patient Safety was formed in 2005 to be the voice of consumer patients. We are determined not to be forgotten collateral damage in a terribly broken healthcare system. Today we are joined by other advocacy groups in a national patient safety movement. Loosely organized through Consumers Union Safe Patient Project, we work together to promote patient safety, improve quality, and protect patient rights. In CT we are working with another patient focused advocacy group – Code Jump Start. We are trying to shine a spotlight on the need to put the patient first and foremost in this vast medical industrial complex and the regulatory agencies that have in the past not always had patients' interests in mind.

We began our work with hospital infections. When I learned in 2005 that there were just two infections reported across 31 hospitals in Connecticut, I knew that it was a good issue to tackle. We were told by hospitals executives with whom we spoke that most infections were "expected", which revealed to me a fundamental gap between consumer and medical facility perspectives. I can assure you that no healthcare

consumer "expects" to visit a licensed medical facility and acquire a deadly infection as a result of receiving care. It was not difficult to amass stories of patients and families and what had happened to them when they had acquired an infection. Keith lost his job, Mary's infected hip replacement put her in a wheel chair for the rest of her life. We brought these stories to our legislature – and legislators added their own stories. Twenty-six states now have legislation requiring public reporting of hospital acquired infections and the Federal government paid attention. There is an impressive nationwide effort to begin to address infections and needless suffering and costs. But think of the individuals who have died and their families loss because medical facilities were slow to react without legislative intervention.

We have learned over the years that legislation has limitations – the healthcare consumers will never get all that we want or all that we deserve. There is absolutely no road map for the consumer patient safety movement and only meager funding for advocates. When funding is awarded for patient safety improvements in the clinical setting, there is seldom a requirement for consumer representation on medical facility commissions, panels, and workgroups studying patient safety innovation and quality improvement. Most funded endeavors exclude patient voices altogether.

While we have worked hard to collaborate with hospitals to get a seat at the table to solve the patient safety epidemic, we concurrently faced obstruction by the industry's powerful and well-funded lobbyists serving profit motives first. We realized we had to think more creatively and decided that nurses make an enormous difference in the quality of care and keeping patents safe. We started an outreach program to nursing schools. Collaborating directly with providers, instead of institutions, seemed a far more positive way to work. Our nursing education program has been successful and continues to grow.

Some doors have now opened and we regularly participate in state and national efforts; however there is much work to be done to bring awareness to an issue that for too long has been accepted by the medical community, overlooked by regulators, unknown to the vast majority of the general public and unsuspecting patients, and out of the realm of consumer protection. Without transparency and accountability, patients will continue to be harmed by medical facilities that tolerate errors at a rate unheard of in other safety sensitive industries.

We are eager to work with medical facilities and the healthcare system, and have just recently begun collaborating with innovators that welcome our participation. Testimony provided later in this Hearing will provide an example of the islands of excellence that have begun to take shape and make progress. But why aren't these islands the norm, instead of the exception?

Several years ago, the Federal Government launched *the Partnership for Patients*. This was an important initiative for healthcare providers but it took two years before patients and patient advocates were even invited to Washington to participate. But then we were told, not to come. There was no money – no money for the patients.

We were sadly an afterthought. Patients and patient safety must be a reflex. Only when we become an equal partner will we begin to see safe patient-centered care.

We thank you Senator Blumenthal for your never-ending commitment to ensure that patients' and consumers' voices are heard.

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Three recent studies

In 2010 and 2011, three much-anticipated new studies on medical harm appeared within six months of each other All three studies used a system called the Global Trigger Tool, developed by the Institute for Healthcare Improvement to mine medical records for signs ("triggers") of potential adverse medical events. All found exponentially greater levels of harm than had been reported by the IOM.

- The Inspector General reported that more than 1 in 4 hospitalized Medicare beneficiaries suffered adverse medical events resulting in some degree of medical harm, and that an estimated 180,000 Medicare beneficiaries a year died from their medical care.
- The Health Affairs study found that one third of admitted patients in three large teaching hospitals suffered medical harm, with many experiencing multiple events. Most of these incidents were flying under the radar, the researchers found. The team from the University of Utah, the Institute for Healthcare Improvement, Missouri Baptist Medical Center, Brigham and Women's Hospital, and Intermountain Healthcare wrote:
- In the New England Journal of Medicine study, 18.1% of patients in ten North Carolina hospitals were found to have experienced one or more adverse medical events. The authors also found that there was no significant change in the rate of harm over the six years of the study from 2002 to

TESTIMONY OF

DR. DAVID BLUMENTHAL

BEFORE

SENATE SPECIAL COMMITTEE ON AGING

HARTFORD, CONNECTICUT

JULY 2, 2012

Senator Blumenthal, members of the Senate Special Committee on Aging, my name is Dr. David Blumenthal. I am currently the Chief Health Information and Innovation Officer at Partners Health System in the neighboring state of Massachusetts, and also Samuel O. Thier Professor of Medicine and Professor of Health Policy at Harvard Medical School. it is a pleasure to appear before you today to discuss how we can use current and potential new health care authorities and policies to improve the functioning of our health care system. My remarks will focus today on initiatives related to health information technology (HIT), but I would be happy after my formal statement to address a broader array of health policy opportunities.

An important point to understand about electronic health information systems is that though they sound and are very technical in certain respects, in other respects they are quite simple. The uses and value of these systems are very easy to understand. Quite simply, HIT is a powerful way to change in positive ways the behavior of all the critical participants in health care – doctors, nurses, hospitals, patients and their families. The power of HIT derives from the power of information, and the ability of electronic systems to put just the right information in front of patients and their caretakers at just the time it can have the most influence and benefits. That information can consist of a wide range of things: basic data about patients' laboratory or other test results and medicines and allergies. Or it can consist of the latest scientific findings from the vast medical literature. Whatever the information, it is the combination of content, timing and availability that make HIT such a potent positive force for change.

Let me give you an example from my own personal experience as a primary care doctor. At Massachusetts General Hospital, all physicians use a decision support tool called Radiology Order Entry, or ROE. When a physician orders a high cost image, like a CAT Scan or MRI, she enters the patient's information in the computer, which automatically compares that information and the order to the American College of Radiology's recommendations for the use of these tests. The computer also searches the patient's record to see if a similar test has been ordered recently. I and many of my colleagues have cancelled or changed many tests as a result of this feedback. The result is improved quality of care, lower cost and less patient radiation exposure – all by providing the doctor with better information. This kind of information system, applied to millions of decisions in many realms of practice, could bend the cost curve down and the quality curve up just by making doctors better at their jobs.

As a result of recent legislation, especially the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, the United States is now embarked on a radical transformation of its health information systems. Every day, doctors, hospitals, nurses and other providers are adopting and using HIT in accordance with federal regulations that reward them financially through extra Medicare and Medicaid payments for becoming meaningful users of certified electronic health records. To date, over 250,000 providers have registered to become meaningful users, and the federal government has provided over $5 billion in incentive payments to nearly 100,000 doctors and hospitals who have attested to meaningfully using electronic records. Rates of adoption of EHRs have doubled in just the last three years.

These accomplishments are dramatic and encouraging, but more could be done. We could build on the HITECH Act and other current health IT authorities in two specific ways: by extending their provisions to cover additional types of providers; and by promoting more sophisticated and powerful uses of HIT once it is adopted. I will say a word about both of these opportunities.

The HITECH Act provides financial incentives to acute care providers – doctors and hospitals and some clinics – but it leaves out professionals and facilities that provide long term care and home care. These are vital parts of the continuum of health care services, and they are particularly important to the care of the 5 percent of Americans who account for 50 percent of health care spending. If we want to improve quality and reduce cost for this very important and very vulnerable segment of our population, then we must provide their caretakers with sophisticated health information systems that can help them coordinate their patients' care. As an example, the Medicare program is now devoting considerable effort to reducing readmissions of patients within 30 days of discharge from the hospital. Many such patients go to long term care facilities or receive home care services. Keeping the providers of such care in touch with the hospital the patients just left could help prevent exacerbations of illness and readmissions. The HITECH Act should be expanded to include providers of long term care, rehabilitation services, home care and behavioral health care.

In addition to adding new types of providers to the HITECH Act, the federal government could increase the impact of electronic health systems by encouraging their more potent use. Two of the most powerful ways to use health information technology is through health

information exchange and the use of clinical decision support. Health information exchange (HIE) consists of sharing information electronically between one provider and another either to care for a patient or to enable the search of multiple records for the purposes of research or quality improvement. Ultimately, the American public could benefit enormously from the creation of a nation-wide infrastructure for health information exchange that could be tapped to mobilize information for the use of caretakers and patients, or to answer questions about such things as drug side effects, patterns of disease spread, environmental health effects and many other queries.

The value of clinical decision support (CDS) is illustrated by the story I told earlier in my testimony. CDS can make doctors and nurses smarter by making sure they take full advantage of the information available in the patient's record, but also in the medical literature. CDS can remind doctors to order indicated preventive care – like mammograms and flu shots -- and patients to request it.

The question is how to encourage the spread and use of HIE and CDS. The best mechanism for doing so is through the definition of the meaningful use of an electronic health record. This definition determines whether clinicians and hospitals get incentive payments or, if they fail to become meaningful users by 2015, whether they will face reduced payments under Medicaid and Medicare, as specified under the HITECH Act.

The responsible federal agencies – the Office of the National Coordinator for Health Information Technology and the Center for Medicare and Medicaid Services – have signaled their intention to increase the requirements for HIE and CDS under meaningful use. However, I

am concerned that as these requirements become more demanding, provider groups may ask the Congress to excuse them from those requirements or delay the financial penalties that begin under current law in 2015. It is essential for the Congress to support the Department of Health and Human Services as it tries to get the most out of electronic health records.

One last area deserves the attention of the Congress and the Executive Branch with respect to electronic health records. This is the development of policies to assure the privacy and security of personal health information in the electronic age. The public must have trust in electronic health records and health information technology generally if we are to take full advantage of these technical breakthroughs. But the current legal framework protecting the privacy and security of electronic health information – the controversial HIPAA framework – is not sufficient. It was created before the electronic age, and does not encompass many users of electronic health information. HIPAA did not anticipate all the threats to privacy and security that have arise as a result of using the Internet to transfer health information, or the problems of cybersecurity that now plague the electronic world. The laws and regulations that underlie consumers protections in the electronic health information sphere need careful review and reconsideration to assure the trust of the American public.

This concludes my formal remarks. I look forward to any questions you may have.

Testimony of Susan L. Davis, RN, EdD

Before the United States Senate

Special Committee on Aging

July 2, 2012

Good Afternoon, my name is Susan Davis and I am honored to participate in today's Senate Special Committee on Aging hearing on exploring next steps to assure the provision of high quality, high value health care across all points of care in our nation's healthcare system.

I am President and CEO of St. Vincent's Medical Center, a 473-bed community teaching and referral hospital that is a member of Ascension Health and of St. Vincent Health Services which includes a 76-bed inpatient psychiatric facility, behavioral health services, special needs services and St. Vincent College. I also serve as Ascension Health's Market Leader, providing strategic and operational leadership, for the New York, Connecticut and Gulf Coast-Florida markets and am Chair of the Ascension Health Information Management Governance Council, which oversees planning and capital investment for health IT across the system and data governance.

Ascension Health is the nation's largest Catholic and largest not-for-profit health system. We have over 1400 healthcare settings that span the full continuum of care, including: critical access hospitals, rural, urban, small and large hospitals; integrated local systems and stand-alone hospitals; and ambulatory care settings, among others.

The enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009 and Patient Protection and Affordable Care Act in 2010 provided an incredible amount of momentum for transformation in the health care delivery system in a very short period of time.

I applaud you for holding today's hearing to assess where we are and what else may need to be done to achieve the vision of a healthcare system where widespread use of interoperable electronic health records (EHRs) supports better clinical care, improved coordination of care, fully informed and engaged consumers, and improved public health.

Ascension Health's Strategic Direction calls us to have a more primary relationship with those we serve by moving to a person-centered approach that fosters the potential to have more continuous, dynamic relationships with those we serve throughout a lifetime. For Ascension Health, this will mean a radical departure from a focus on providers delivering episodic medical services to patients to a focus on developing trust-based relationships with people that transcend an individual healthcare encounter and promote spiritually-centered, holistic approaches to supporting their broader health and well-being needs. A person-centered approach will involve a shift in the locus of control from providers to people, their families and other trusted resources. It will also require a transition in Ascension Health's sites of care, from primarily hospitals and clinics today to more care and support occurring in the community, in the home and through virtual means.

Embracing a person-centered approach creates significant opportunities to create value for those we serve, and for the purchasers of healthcare. To create this value, we will need to focus on clinical utilization, optimizing the location of care across the continuum and the type of caregiver delivering the care, and focus more broadly on care coordination and chronic disease management. We will also need new relationships with purchasers of healthcare (e.g., commercial payers, governmental payers, self-

insured employers) that equitably reward us for the value we create. Models that allow providers to participate in the value created include pay-for-performance, bundling, shared shavings programs and capitation.

To date, Ascension Health has invested close to a billion dollars in our EHR journey and committed more than $170 million in additional capital investment – not including operating expenses – to support our hospitals in reaching Meaningful Use Stage 1. As of May 2012, 13 Ascension Health hospitals have achieved Stage 1 Meaningful Use, three of which were early adopters that reached the Stage 1 milestone in 2011. We expect that by the close of federal fiscal year (FFY) 2012 28 of our hospitals will achieve Stage 1 Meaningful Use and Ascension Health will earn a total of approximately $120 million in incentive payments. Additionally, Ascension Health has fifteen hundred ninety eight (1,598) employed eligible professionals who are working to achieve Stage 1 Meaningful Use by the end of calendar year ("CY") 2012 for an estimated $68 million dollars in incentive payments.

St. Vincent's successfully attested to Stage 1 Meaningful Use for the hospital in April 2012. The total incentive opportunity over four years for the hospital (Medicare and Medicaid combined) is $10.1 million ($8.3 million Medicare, $1.8 million Medicaid).

Ascension Health was a founding partner of the CMS Partnership for Patients program launched in April, 2011 and is one of 26 awardees – and one of only a handful of health systems – that was awarded a CMS Hospital Engagement Network contract. As you know, the Partnership for Patients is a nationwide public-private partnership that offers support to physicians, nurses and other clinicians to make patient care safer. Under the Hospital Engagement Network contract, we are providing intensive training programs to teach and support other hospitals to make patient care safer.

Two of our local health systems were designated Pioneer ACOs in Texas and Michigan last December.

I mention these accomplishments to say that we are fully engaged in the journey to a transformed high quality, high value health care system.

Ascension Health is a member of the Bipartisan Policy Center (BPC) that issued a report earlier this year on the role of information technology in transforming health care. The BPC is a nonprofit organization founded by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole and George Mitchell in 2007 and is the only policy-oriented think tank that promotes bipartisanship on key issues challenging our country.

The BPC report highlighted a number of issues that must be addressed if we are to be successful in building an electronic infrastructure to support high quality, high value health care across all points of care in our nation's healthcare system. They include aligning incentives with higher quality, more cost-effective care; accelerating the electronic exchange of information across the many settings where care and services are delivered; expanding engagement of consumers using electronic tools; expanding education and implementation assistance; further clarifying policies related to privacy and security; and aligning requirements across federal health care programs.

New delivery system and payment reforms that promote high quality, high value care require coordination of care among the many providers that deliver care to a patient and bringing important health care information about the patient to the point of care, to support clinical decision-making. Because of the fragmented nature of the U.S. health care system, the information that is needed to support care coordination and better health care decisions resides in multiple settings where care and

services are delivered, including the offices of primary care physicians and specialists, hospitals, laboratories, pharmacies, radiology centers, nursing homes and long-term care settings, health plans, and even with the patient.

While there has been significant progress with the adoption of electronic health records—largely due to HITECH—to date, very little progress has been made with the interoperability of health IT systems and the exchange of critical health information—such as medications, laboratory test results, and radiology test results—about a patient, to support better clinical decision-making and coordination among the care team. I would like to highlight two issues that must be addressed to promote the exchange of information to support coordinated, accountable, patient-centered care: accelerating the interoperability of EHR systems and improving the accuracy of patient matching.

HHS has made considerable progress in advancing standards for interoperability but more action is needed. Standards and certification requirements associated with CMS' Medicare and Medicaid Electronic Health Record (EHR) programs should be expanded in Stage 2, to require additional data transport and data content standards to support interoperability of EHR systems and exchange of information across settings in which care and services are delivered.

Clinical IT vendors have proprietary standards which prevent easy data exchange between systems – and, frankly those proprietary practices can serve as a barrier. U.S. banks figured this out a long time ago. Without standards, investments made in HIT are minimally optimized increasing the overall cost of health care delivery.

In addition, other changes are needed to enable healthcare providers to be sure that the information they receive about a particular patient is accurate. The Bipartisan Policy Center illustrated the problem in their recent report, "*Challenges and Strategies for Accurately Matching Patients to their Health Data*." "In Harris County, Texas there are 2,400 people named Maria Garcia. Two hundred thirty-one of them have the same birth date. In that county alone, there are almost 70,000 pairs of patients who share both names and birth dates." This is not a problem that is unique to Harris County, Texas, or to Texas. National estimates on error rates as a result of patient misidentification vary from 8 percent up to 20 percent. Obviously, if a health care provider receives information on the wrong patient, medical errors will occur. Additional standards and policies are needed to support improvements in the accuracy of methods used to match patients to their health records.

While patient matching is not a new issue, passage of the HITECH Act and the resulting acceleration of the electronic capturing and the desired sharing of information to improve patient safety, eliminate redundancy of medical testing, and better coordinate care across settings has put this issue back on the national agenda with renewed urgency. In 1996, when Congress passed the Health Insurance Portability and Accountability Act of 1996, Congress authorized work on the development of a unique patient identifier. But concerns about private and security eventually led to legislation in 1999 that prohibited the Administration from developing a unique patient identifier.

Hospitals and other health care providers "work around" not having a national strategy on patient matching through a variety of less than desirable methodologies. One strategy relies on establishing algorithms that identify patients using multiple patient attributes. But this strategy is often compromised by data fields that are outdated (such as a change of address) or inaccurate. And this strategy is costly. At Ascension Health, our larger health care systems have at least 2 dedicated Full Time Equivalents (FTEs) to help manage this process. A survey conducted by the College of Healthcare

Information Executives (CHIME) found that between 0.5 to 20 FTEs are needed to facilitate patient matching, dependent on an organization's size. There must be a national strategy to improve rates of accuracy matching patients to their health information while ensuring the privacy and protection of personal health information. As the Senate sponsor of S. 1535, the Personal Data Protection and Breach Accountability Act of 2011, you especially aware of the need to ensure patients and providers that personal health care information is kept secure and confidential.

I would like to close with a final thought on alignment of federal quality measures.

CMS offers three ways for providers to begin moving to providing accountable care under its newly created Accountable Care Organization (ACO) program: the Medicare Share Savings Program, the Pioneer ACO program, and an Advanced Payment Initiative. All three versions of these ACO programs report on identical quality measures, and the requirements on how the measures are collected and submitted are also identical. The Final Report on *"Accountable Care Organization 2012 Program Analysis on Quality Performance Standards"* submitted to CMS last December noted that the "ACO quality measures align with those used in other CMS quality programs" including the Electronic Health Record Incentive Program and that CMS "listened to industry concerns about focusing more on outcomes." We applaud this growing awareness at CMS and of other policymakers on the importance of focusing on patient outcomes and aligning quality reporting measures with other federal program quality measures. The burden on providers related to mandated reporting on multiple, unaligned quality measures across several federal programs (further complicated by value and performance programs sponsored by commercial insurers) should not be underestimated.

The broader U.S. healthcare system needs to align both its payment and technological processes to assure high quality and high value across all points of care. Health IT and provider adoption of EHR technologies must become an integrated component of health system transformation that is grounded in policy which facilitates provider access to secure patient health information.

I welcome the opportunity to serve as a continuing resource to you in this important work. Thank you for inviting me to testify this afternoon.

U.S. Senate Special Committee on Aging
Congressional Field Hearing
Hartford, CT
July 2, 2012

Testimony of Ms. Jamesina E. Henderson, Chief Executive Officer, Cornell Scott-Hill Health Corporation

Thank you, and good afternoon. Senator Blumenthal, thank you for the opportunity to contribute to your research on this most important subject. I am Jamesina Henderson, CEO of the Cornell Scott-Hill Health Corporation, Connecticut's first Federally Qualified Health Center and one of its largest.

We were established in 1968 as a primary care institution and through our 44 years of growth, expansion and development of services in medical, dental and behavioral healthcare, we have become the nation's best example of integrated care. We are not alone in arriving at this conclusion. Linda Rosenberg, CEO of the National Council, who visited with us recently and is responsible for leading an association comprised of over 1,900 behavioral healthcare organizations nationwide, stated that in all of her experience we are the best example of integrated care that she has ever seen. I believe our perspective on care integration is critical to your effort on patient safety and I'd like to explain why.

Throughout our history of providing care to the 33,000 people who consider us their medical home each year, we have focused on delivering a quality experience from scheduling to the reception desk to the treatment room. One of the challenges we have faced is ensuring the appropriate sharing of information between our medical, dental and behavioral health providers. Many of our patient population receive services from all three disciplines. And as many of you know, there are many connections between mental health and physical health.

In one of our most recent efforts to tackle this problem head-on, which is what we like to do at Cornell Scott-Hill Health Corporation, we challenged the marketplace to provide what we know is the right contributory solution to improved patient care and patient safety – a completely integrated electronic health record structurally built on a foundation of information sharing across all three care disciplines.

We demanded a solution that mirrored our practice of integrated care. And only one solution provider heard our call. I am proud to say to this committee that the Cornell Scott-Hill Health Corporation, in partnership with General Electric, is leading the transformation of electronic health records. Our system, which is now in place at several of our 16 care sites, is likely the first in the nation to provide full integration and sharing of information across all care disciplines.

We know from experience that communication and sharing of information is critical to patient safety, continuity of care, and to an enhanced patient experience. Technology aside, there are other ways we know this to be true. And like the technology solution we are implementing, there are other collaborative and partnership solutions underway in our healthcare environment equally deserving of mention.

Today we have no less than three programs in place, funded through foundations and others, to provide patient navigation services to patients with specific conditions. Just last month we were awarded a grant from the Komen Foundation to provide patient navigation services to women with breast cancer.

What these foundations know and are willing to put their funding behind is the true value of communication, information sharing and care management. They know that if patients diagnosed with specific conditions are assisted along the path of the healthcare continuum, they stand a better chance of improved health outcomes.

Technology cannot do this alone – it is an important, even critical component, but the human component is needed. Patients need to know they have an advocate fighting for them, working with them to ensure their needs are going to be met.

This gains increasing importance as the population in general, and our patient population specifically, ages. More complex medical conditions and treatment regimens, including medication adherence, demand greater attention.

Patient navigation is a clear success story. With it, we stand a better chance of our patients receiving the right care at the right time in the right place. Patient navigation can help us reduce non-emergent visits to emergency departments which of course everyone knows will reduce costs throughout the healthcare system.

What makes this a difficult solution to implement is the simple fact that patient navigation services are not a reimbursable expense from our current payer mix. Another challenging aspect to providing this service is the lack of training and workforce development opportunities to help us transform the existing workforce into 21st century care-givers capable of coordinating care across multiple specialties and institutions while simultaneously delivering on our promise of an exceptional experience.

I'd like to make one additional point before concluding with a recommendation. All of us in the healthcare field understand the growing complexities in delivering quality care. With the confirmation of the Affordable Care Act, we know the future of healthcare is going to be different tomorrow than it is today. One area we know will not be different is the expectation of our patient – high quality and safe care from their provider.

We believe the vast majority of our patients have elected to make us their medical home precisely for that reason. A medical home is more than a label. It is an

affirmation of expectation and of value. And underpinning that expectation and acceptance of a medical home is - *trust.* The simple and powerful truth is that our patients place their trust in us, all of us in the healthcare field, to do what is best for them. A successful hand-off or transfer of a patient, and their clinical information, builds trust. And when coupled with the overt acceptance of responsibility for an individual's care, then and only then have we all succeeded in transforming healthcare.

My recommendation to you, Senator Blumenthal, and to your colleagues on this committee and in the Senate, is to draft legislation that supports our efforts to provide seamless, accountable and beneficial patient navigation across the healthcare spectrum. With it, we can improve patient safety, achieve better outcomes and reduce costly interventions.

Once again, thank you for the opportunity to share my thoughts on this most important issue.

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Scott Ellner, DO, MPH, FACS

Director of Surgical Quality
Saint Francis Hospital and Medical Center

Assistant Professor of Surgery,
University of Connecticut Medical School

Testimony July 2, 2012

A Surgeon's Perspective on Value Based Health Care Delivery

Value

As a general and trauma surgeon employed at Saint Francis Hospital and Medical Center in Hartford, Connecticut, I am honored to share with the Committee our journey to improve the value of health care delivered to our patients.

Value is equal to health outcomes per health dollars spent (or costs).

This value proposition succinctly redefines the next steps toward health care reform and, importantly, it can be achieved through the full continuum of care as identified by the Triple Aim – that is, simultaneously improving the experience of care for patients and their families, improving the health of populations, and reducing per capita costs of healthcare.

Outcomes

My vision as a health care provider is about improving outcomes. It's a well-known management axiom that if something is not measured then it cannot be improved. At Saint Francis, over the last 5 years my team has collected and reported on 30-day surgical complications through a risk-adjusted, transparent database. Knowing our outcomes has allowed us to realize both "how good we are...and how much better we can be"

Over this time period, using our data, we have implemented specific patient safety initiatives to improve our patient outcomes.

Examples include:
1)Nurse-driven protocols for early removal of catheters to prevent urinary tract infections (Result: 62% reduction in urinary infection rates)

2)Improved care bundles in the intensive care units to prevent pneumonias (Result: 33% reduction in pneumonia rates)

3)Development of an operating room team training program to effectively implement a surgical checklist to prevent safety-compromising events during the peri-operative process (Result:70% reduction in post-op complication rates and recognition by the Joint Commission for demonstrating "Best Practice" for Time-Out in the OR)

Costs

Knowing our outcomes has allowed us develop these performance improvement initiatives to prevent costly readmissions and health care acquired infections---the disutility of care. We found in one study that, on average, an inpatient developing a C. Difficile infection added an excess cost of $54,000 to their care.

By obtaining better outcomes, we can identify opportunities to eliminate waste and reduce costs. Through our electronic health record, information is now streamlined so that we can automate our data collection for real-time monitoring and make adjustments.

The Culture

We have to be prepared to change a culture. The behaviors and actions of the doctors of today come from the core curriculum in the medical schools and residency training programs. We are still taught 19th and 20th century management principles toward human interaction. Consequently, there is a hierarchy or authority gradient in medicine which can impede communication and collegiality among all providers. It's time to level this authority gradient so that we work together as a cohesive unit.

At the University of Connecticut School of Medicine, we have now implemented a patient safety curriculum to teach the future providers of health care how to be the best advocates for their patients and work together as an integrated unit along the continuum of care.

At Saint Francis Care, in March of this, year we had an extremely successful Patient Safety Awareness Day with the goal of collaborating with our patients so we could help them safely navigate the health care system for themselves and their families.

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TESTIMONY
For The Record

Next Steps for Patient Safety: Assuring High Value Health Care Across All Sites of Care

Legislative Office Building
300 Capitol Avenue Room 2C
Hartford, CT

July 2, 2012

Statement of

Sean M. Jeffery, PharmD, CGP, FASCP

President-Elect
American Society of Consultant Pharmacists

Before
Senator Richard Blumenthal (D-CT)
and the
Special Committee on Aging
The United States Senate

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Senator Blumenthal:

On behalf of the American Society of Consultant Pharmacists (ASCP), thank you for the opportunity to submit this statement for the record on medication safety for older adults. This testimony will highlight the important role pharmacists play in improving the quality of care while reducing health care costs for older adults. I am Sean M. Jeffery, PharmD, CGP, FASCP, President-Elect of ASCP and Associate Clinical Professor at the University of Connecticut. I hold a Bachelor of Science degree in Pharmacy from the University of Connecticut and a Doctor of Pharmacy degree from The Ohio State University. I completed a specialty pharmacy residency in geriatrics at the Duke Center for the Study of Aging and the Department of Veterans Affairs Durham (VA) Medical Center.

My practice site is located at the VA Connecticut Healthcare System's West Haven campus where I serve as pharmacist for the interdisciplinary geriatric consult service and Geriatric Pharmacy Residency Program Director. This collaborative practice delivers comprehensive evaluation and health care management for patients over the age of 75 throughout the VA Connecticut healthcare system. I am also an adjunct faculty member at Yale University School of Medicine, Geriatrics Section. I have served as chairman of the Geriatrics Special Interest Group for the American Association of Colleges of Pharmacy and I am also one of the founding coordinators for the Senior Symposium meeting held annually by the Connecticut Chapter of ASCP.

Currently, I am involved in a VA health research study investigating pharmacists-led, group diabetes care for patients with high cardiovascular comorbid risks. The Multi-disciplinary Education in Diabetes and Intervention for Cardiac risk reduction (MEDIC) shows that pharmacists improved overall diabetes care while reducing costs. Additionally, I am investigating the role of medication complexity with regards to cognitive decline in older adults. In an effort to improve medication prescribing at the community level, I have co-founded the Senior Safe Medication Project with the Yale University School of Medicine. The goal of the New Haven Senior Safe Medication Coalition is to improve medication prescribing practices for the citizens of New Haven. This unique public/private partnership is developing a public service announcement specifically aimed at patients and providers in New Haven, CT.

In addition to my work at the University of Connecticut School of Pharmacy, I frequently receive calls from Connecticut citizens seeking help in managing their medications. Often overwhelmed by the sheer number of medications, these patients seek the expertise of consultant pharmacists to help simplify their medication regimens. To address their concerns I provide medication therapy management (MTM) consultations on a fee-for-

services basis. As a pharmacist I provide consultant services to VA inpatients and outpatients, private individuals in the community and to governmental and regulatory agencies. This opportunity to work in a variety of care delivery models in various settings where geriatric patients reside, including hospitals, long-term care (LTC) facilities and outpatient settings makes me uniquely qualified to testify about medication-related problems in older adults. I consider myself a senior care pharmacist who is personally invested in patient safety for geriatric patients by assuring optimal medication therapy. Consultant and senior care pharmacists are situated at the nexus of care transitions for older adults. We are key providers who medication safety and care delivery for seniors where ever they reside.

WHAT IS A CONSULTANT PHARMACIST

Consultant pharmacists work across the continuum of care, serving long-term care and assisted living facilities, hospice and palliative care programs, psychiatric hospitals, home and community-based care settings, and home-infusion companies. Recognized as experts on the use of medications in older adults, consultant pharmacists focus on improving the quality of life of geriatric patients by optimizing medication management in this at-risk population. Consultant pharmacists play a critical role in patient-centered health care delivery models as part of the geriatric interdisciplinary team of medical experts. They ensure the appropriate and optimal use of medications by older adults within institutions and in the community, along with providing advice on the provision of pharmacy services to patients residing in institutions.

The traditional consultant pharmacist provides clinical services in the nursing home setting such as medication regimen reviews, observation of medication passes, and medication reconciliations during and after transitions of care. Consultant pharmacists are effective educators who ensure that the nursing facility healthcare team, families and residents understand important aspects of medication use in the frail at-risk elderly. They help facilities monitor as well as optimize the use of potentially dangerous medications such as anticoagulants, psychoactive agents and anti-diabetics. Residents of nursing facilities often have multiple chronic conditions such as diabetes mellitus, dementia, and cardiovascular-related illnesses, which lead to increased medication burden. Consultant pharmacists' core strength is expertise in geriatric pharmacotherapy and the unique medication-related needs of nursing facility residents.

In their role as MTM experts in the community, consultant pharmacists meet with patients and collaborate with doctors, nurses, family members and caregivers to evaluate, manage, and optimize medication regimens for older adults living in community settings. Their skills, knowledge and experience are essential for appropriate, safe, and effective use of medications, particularly in the frail at-risk elderly. Because consultant pharmacists assist their patients and caregivers with ensuring that their prescribed drugs are appropriate for

their condition and taken correctly, medication-related problems are minimized and overall health care costs are reduced.

THE VALUE OF THE CONSULTANT PHARMACIST

The value of a consultant pharmacist in ensuring patient safety is indisputable. One of the consultant pharmacist's primary focuses is to ensure the appropriateness of prescribing by identifying potential contraindications, potentially inappropriate medications, and adverse drug events, and ensuring adequate medication monitoring. Medications can improve health and quality of life, of course, but the likelihood of harm also increases with increasing patient age. One study has reported that among older Americans (aged 60 years and over), more than 76 percent used two or more prescription drugs and 37 percent used five or more. The percentage of persons who used five or more prescription drugs increased from 6 percent in 1999–2000 to 11 percent in 2007–2008. With nearly 40 percent of older Americans using five or more prescription drugs per month, issues of adverse drug events, non-adherence, and increased cost become more common[i]. Consultant pharmacists must balance treatment needs with the risks associated with using multiple medications. Overall, consultant pharmacists play an integral role in ensuring that medications are prescribed appropriately in the nursing facility. Older adults in nursing facilities use at least nine or more medications.

As a key element of the interdisciplinary team, consultant pharmacists provide expert pharmacotherapy management recommendations. This expertise reflects a comprehensive understanding of the established best practices involving pharmacokinetic and pharmacodynamic changes associated with aging and with having multiple chronic conditions. With patient care as the focus, pharmacotherapy recommendations also encompass promoting cost-effectiveness, ensuring medication safety, and reducing prescription waste. Consultant pharmacist-conducted drug regimen reviews improve optimal therapeutic outcomes for nursing home residents by 43 percent. In addition, consultant pharmacist-conducted drug regimen reviews save as much as $3.6 billion annually in costs from prevented medication-related problems[ii].

Most consultant pharmacists maintain long-standing relationships with nursing facilities, allowing them the unique perspective of caring for individual residents longitudinally. Consultant pharmacists participate in interdisciplinary quality assurance committees and resident care-planning. Whereas staff turnover presents challenges to certain areas of long-term care, the consultant pharmacist profession represents a reliable, stable workforce. Robust medication databases developed by the industry allow both retrospective and prospective analyses of medication trends and variances. Taken together, consultant pharmacists are indispensable members of the healthcare team in their role of managing older adults' medication regimens. As new practice models are developed for the senior population, the consultant pharmacist must be an integral part of

the interdisciplinary team.

THE AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

ASCP is the international professional society of over 7,000 consultant pharmacists and about 4,500 students whose mission is to promote the appropriate, safe, and effective use of medications in the elderly. ASCP's members provide long-term care and consultant pharmacist services to seniors and individuals with chronic illness in a variety of environments, including nursing facilities, sub-acute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care. ASCP has a long history of advocating for the medical best interests of seniors who reside in nursing facilities, the community, and those enrolled in hospice programs.

The vision of ASCP is to provide optimal medication management and improved health outcomes for all older persons. Our mission is to empower pharmacists to enhance quality of care for all older persons through the appropriate use of medication and the promotion of healthy aging. Through ASCP, our members have access to professional development, education, and resources in order to address the medication-related safety needs of their patients. This provides them with unique geriatric expertise to achieve goals of therapy for their patients.

In 1997, ASCP developed the Commission for Certification in Geriatric Pharmacy (CCGP), a national voluntary certification program for pharmacists. This Geriatric Pharmacy Practice certification program offers a certification credential for eligible candidates that successfully complete a written examination. A pharmacist who is certified in geriatric pharmacy practice is designated as a "Certified Geriatric Pharmacist" (CGP). To become certified, candidates are expected to be knowledgeable about principles of geriatric pharmacotherapy and the provision of pharmaceutical care for the elderly. CCGP requires all Certified Geriatric Pharmacists to recertify every five (5) years.

MEDICATION SAFETY

To properly address patient safety, it is imperative to understand how a patient's medication regimen can affect their safety. Approximately 800,000 preventable adverse drug events occur each year in nursing facilities. In hospitals, the number of preventable adverse drug events has been estimated from 380,000 to 450,000 preventable adverse drug events[iii] each year. These errors can occur at any step in the medication use process: prescribing, order communication, dispensing, administering, adherence, and monitoring. As the medication experts for the geriatric population, consultant pharmacists can greatly decrease the likelihood of an adverse drug events at each step in the medication use process through their recommendations, verifications, proper documentation of

communication among health care professionals, and drug therapeutic monitoring.

In a collaborative effort to reduce the number of preventable adverse drug events, consultant pharmacists work with the American Geriatric Society (AGS) to maintain the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (last updated in 2012)[iv]. Seven of the 14 members of the AGS Beers Criteria Panel were geriatric pharmacists[v]. Beers criteria are used to decrease the use of potentially inappropriate medications in older adults, and serves as a guide for geriatric practitioners to aid in identification of medications for which the potential risks may outweigh the potential benefits for older adults.

DRUG SHORTAGES

A well-publicized patient safety risk we are faced with today is the increasing shortages of critical life-saving drugs. When medication access problems create delays in administration, or force an abrupt change in medication therapy, patients are at risk of the potential for fragmented or incomplete drug therapy. From 2005 to 2010, the number of drug shortages reported by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research increased from 62 to 172 drug shortages. As of November 30, 2011 there were 251 reported shortages, with 80 percent involving sterile injectables[vi]. According to the FDA, "...these shortages have involved cancer drugs, anesthetics used for patients undergoing surgery, as well as drugs needed for emergency medicine, and electrolytes needed for patients on [intravenous] feeding."[vii]

Nursing facility residents and patients in other settings requiring drug infusion services needlessly suffer the consequences of these shortages, even though many generic sterile injectable drugs are inexpensive. Many older adults rely on these types of medications to treat complex chronic conditions, and subsequently are at a greater risk of adverse drug events and suboptimal health outcomes. When critical drugs are substituted with less desirable alternative drugs or dosage forms because of shortages, the consequences may be dosing errors, product mix-ups, cancellation or postponement of procedures, undesirable side effects of alternative agents, and even deaths[viii]. Consultant and senior care pharmacists are committed to supporting efforts to address our nation's drug shortage problem and to educating other health care professionals on managing drug shortages.

My wife is the assistant director of pharmacy overseeing clinical pharmacy operations for a 500-bed community hospital in Connecticut. In her role she continually struggles to manage drug shortages. Her facility also has an attached long-term care unit. Therefore the challenges of drug shortages extend to both the acute and chronic care settings.

TRANSITIONS OF CARE

Our nation's health care system is fragmented. The ability for multiple health care providers to effectively communicate and coordinate care across and among physicians' offices, acute care hospitals, and nursing facilities, can be challenging under the existing standards for care delivery models. In recent years, a number of new concepts and health care delivery models aimed at reducing unnecessary readmissions due to poor care transitions have evolved.

Approximately 80 percent of patients transitioning to a new care setting have at least one medication reconciliation or adherence issue upon discharge from their previous setting[ix]. Patients undergoing transitions of care should have access to a consultant pharmacist to reconcile multiple medication lists and pill bottles and to develop an optimal medication regimen to avoid unnecessary and costly readmissions or adverse drug events. Consultant pharmacists can also work with patients and their caregivers to address and improve medication adherence. I frequently identify patients who have stopped taking their medication for chronic conditions such as hypertension, diabetes, high cholesterol and Alzheimer's disease. By carefully reinitiating therapy, and advising providers to the interruption in therapy, I help mitigate healthcare costs and improve health outcomes. Unfortunately, many patients stop or never even fill prescriptions ordered by their provider. Consultant pharmacists are uniquely trained to identify gaps in adherence. By performing a comprehensive medication evaluation I uncover gaps in care, the need for dosing adjustment, drug-drug interactions risks, and therapeutic duplications. Coordination during care transitions with the other members of the health care team that includes medication regimen optimization improves risks to patient safety. Consider what happens to a patient who stops taking their medication but doesn't alert their providers. If this person is admitted to the hospital, they will be restarted on their outpatient medications with potentially disastrous results. In my role as a consultant pharmacist in the hospital, I routinely see "forced-adherence" adverse drug events occurring after reinitiating medications that patients stopped without notice.

The foundation for improving care transitions and patient safety relies upon the implementation of health information technology and the meaningful use of electronic health records (EHRs). The passage of the Health Information Technology for Economic and Clinical Health Act (HITECH) of the American Recovery and Reinvestment Act (ARRA) of 2009 included reimbursement incentives designed to stimulate the adoption of EHRs by health care providers. Implementation and use of EHRs improves patient safety by facilitating the ability for patient care to be coordinated longitudinally and across multiple care settings. However long-term providers, post-acute care providers, and pharmacies are not eligible for these incentives despite their critical roles during care transitions. ASCP, along with other stakeholders throughout the long-term care and post-acute care professional community are working together under the auspices of the Long-term and Post-Acute Care Health Information Technology Collaborative (LTPAC-HIT) to encourage

expansion of the meaningful use of the EHR incentive program to long-term care and post-acute settings. ASCP is also working with other pharmacy stakeholders under the umbrella of the Pharmacy Electronic Health Information Technology Collaborative (Pharmacy eHIT). Working within the VA healthcare system I am fortunate to have access to a fully integrated EHR. When I consult in the community I lack the access to data that ensures my recommendations are as comprehensive as possible. It is as if I am driving blind.

ANTIPSYCHOTIC MEDICATION USE IN NURSING FACILITY RESIDENTS

Approximately 25 percent of nursing facility residents receive antipsychotic medications. In this population, antipsychotics are generally used for three purposes:

- Treatment of psychotic disorders (e.g. schizophrenia)
- Treatment of psychotic symptoms (e.g. delusions, hallucinations) associated with other conditions (e.g. depression, Parkinson's disease or delirium)
- Treatment of behavioral and psychological symptoms associated with dementia (BPSD), when these symptoms present a risk of harm to the resident or others

More than half of nursing facility residents are diagnosed with some form of dementia, and many of these residents experience BPSD. The preferred therapies for management of these symptoms are non-pharmacologic, including environmental modifications. If an underlying cause or reason for the behaviors can be identified, a non-pharmacologic approach that addresses this underlying cause can be effective and safe.

Medications for the treatment of BPSD should only be considered in emergency situations, where rapid action is needed to prevent harm, or when non-pharmacologic strategies do not achieve resolution of the problem. When used, medications should generally serve as an adjunct to non-pharmacologic measures rather than as an alternative.

Prior to initiation of drug therapy, expected benefits and potential risks of the medication should be considered and discussed with the patient and/or family or legal guardian. The class of medications with the best evidence of benefit in older adults with dementia is atypical antipsychotics. However, these medications have significant risks in this population, including an increased risk of mortality.

ASCP has a long history of working with CMS to develop and implement guidelines for use of antipsychotic medications in nursing facility residents. Current guidance from CMS to nursing facilities on the use of these medications is found in Appendix PP of the State Operations Manual, especially pages 383-389 in Table 1 at tag F329.

ASCP, in conjunction with the Long-Term Care Pharmacy Alliance, the National Community Pharmacists Association, and the Pharmacy Quality Alliance, submitted a letter November 9, 2011 to CMS on the subject of antipsychotic drug use in nursing facilities. In addition to

providing a summary of current initiatives already in progress, the letter also contains a summary of existing tools and resources available to the public as well as recommendations for future programs and areas of study[x].

On March 29, 2012, the CMS announced an initiative to improve behavioral health management and to safeguard nursing facility residents from unnecessary antipsychotic drug use. A goal was established to reduce antipsychotic drug use by 15 percent by December 2012. This initiative was launched with a video webinar, which includes a presentation by ASCP, along with the medical director, prescriber, nursing staff and resident perspectives on the use of antipsychotics in nursing facilities.

Consultant pharmacists regularly work with physicians and nursing facility staff to help reduce doses and discontinue antipsychotics when feasible to ensure patient medication safety. ASCP has also established a Web page with more information and resources about the use of antipsychotics in residents of nursing facilities. This page is available at: http://www.ascp.com/antipsychotic.

INNOVATIVE HEALTH CARE MODELS

The Affordable Care Act (ACA) includes a number of programs that encourage the incorporation of clinical pharmacist services in innovative care delivery models in order to improve patient safety, care quality, coordination, and health outcomes. Among the most notable programs is the **Accountable Care Organization** (ACO) Shared Savings Program. Qualified ACO participants (e.g. hospitals, physicians, pharmacists and other health care providers) must demonstrate their ability to deliver quality and efficient care evaluated by performance benchmarks that are reported to the Centers for Medicare & Medicaid Innovation (Innovation Center). Participating ACOs that meet or exceed care quality performance benchmarks through avoiding duplication of services, elimination of unnecessary medical care, and limiting the need for acute care services will receive enhanced reimbursement based on the savings realized by reduced costs. A successful ACO model will include clinical pharmacists charged with optimizing drug therapy for patients and ensuring medication adherence.

The **Patient Centered Medical Homes** (PCMH) is not a building or a place, but a care delivery model in which health care providers as part of an interdisciplinary team work with patients, families, and caregivers in order to provide comprehensive coordinated care to continuously improve patient outcomes and ensure patient safety. The PCMH model has seven principles which include: personal physician, physician-directed medical practice, whole person orientation, integrated/coordinated care, quality and safety, enhanced access and payment. A successful PCMH will incorporate pharmacist-provided comprehensive medication services to optimize patient medication regimens and avoid costs associated with poor adherence of medication-related problems.

Finally, the **Independence at Home** (IAH) Demonstration is an innovative care delivery model that allows frail elderly patients that are at risk of, or would otherwise be placed in a nursing facility to receive high-quality care in the comfort of their own home. Having spent 8 years working on a home-based primary care team within the VA Connecticut Healthcare system, I routinely visited patients in their homes. This model of care provides high quality of life, and perhaps the most realistic understanding of the needs of our patients. The IAH Demonstration represents an opportunity to improve quality of life for patients in the community with cognitive and physical limitations while receiving the level of care they need. Goals of the IAH Demonstration include: improved care coordination; reduction in emergency department visits; and decreased incidents of preventable hospitalizations and hospital re-admissions. Various studies have shown evidence that IAH models have cost savings benefits. As with nursing facilities, consultant pharmacists have a natural role in the IAH care model in that regular reviews and optimization of medication regimens would likely result in avoiding drug-drug interactions, unnecessary drugs, and reduced costs to the patient and the health care system. Moreover, consultant pharmacists are the best qualified to help patients establish medication management protocols that are simple, easy to follow, and ensure appropriateness of dosing, timing and relationship to food and other factors that can affect drug absorption.

Thank you once again for the opportunity to submit a statement for the record regarding patient safety and how consultant and senior care pharmacists are uniquely positioned to address many of the needs in today's geriatric population. Consultant pharmacists have a demonstrated track record of improving patient safety and saving health care dollars through expert geriatric management.

Please do not hesitate to contact me with further questions at Sean.Jeffery@gmail.com or Lynne Batshon, Director of Policy & Advocacy at ASCP, via email at LBatshon@ascp.com.

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Special Committee on Aging'
Next Steps for Patient Safety: Assuring High Value Health Care Across All Sites of Care
Date : July 2, 2012 Time: 1pm start

First Hand Account Statement and Testimony

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My name is Gail Simon. I am the daughter of Helen M. Simon (87) who has been a nursing home resident of previously family owned Saybrook Convalescent Hospital in Old Saybrook, CT. since May 2009. One year later this 120 bed facility was purchased by a for-profit corporation which now owns 26 of Connecticut's 234 nursing homes. I have visited my mother every day the first two years. This third year I am visiting her with a much greater understanding of the complexities that exist between staff and the inability of the direct care workers to speak out without a fear of losing their job. I am also the Family Council Representative at this nursing home which advocates for approx 90 long term care residents. We are six months new and have approx 10 families which attend monthly meetings. It has not been easy.

First I am told that our Family Council is 1 of only 3 Family Councils which meet privately and independently of the nursing home. Most family councils in the State of Connecticut if you can find them are run by the administrators of the facility. I submit that if a nursing home advertises they have a "family council" and is in fact facilitating the family council then that could be considered a conflict of interest or perhaps not a true family council in comparison to a private and independent family council. Family Councils are not promoted in Connecticut, family members are confused as to what a family council is and family members are often too busy to become involved in their loved ones care. Although Federal regulation 483 15(c)(1-5) states a resident's family has the right to meet in the facility with other families in the facility and that "the facility must listen to the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility" this does not often get documented and therefore quality of care and quality of life concerns are not resolved. One of the reasons there is no resolve is the fact that when an Independent Family Council wants to take action and does so by documenting a concern on what is called a Family Council Action Form, there is no written State or Federal regulation yet stating a reply must be given within a defined period of time. Three weeks is a fair amount of time for a designated staff person to come back with some written answer addressing the concern submitted by the Independent Family Council. Obviously family councils which are facilitated and are run by the facility have no interest in documenting their own flaws. It's a new day and new ideas can be achieved without any financial burden Since an Independent Family Council meets privately, it can listen to grievances of other families without fear, can work with the facility to come up with solutions and can save the facility costs by being part of the culture change needed to support staff in speaking up about resident care A facility run family council does not encourage nursing staff to speak up. And if they did the staff would tell you as they have told me that they do not have enough staff on the schedule to give the standard of care Connecticut should empower the Independent Family Council by protecting the right to recruit new family members, the right to know how many staff are scheduled on each shift on each unit, the right to form other Independent Family Councils within the structure of a for-profit corporation and the right to have a written reply to a documented concern within three weeks

As Family Council Representative our family members are trying to communicate concerns to facility administrators and work on solutions and improvements but it is obvious that the corporate structure dictates how the facility is staffed and budgeted. Corporate profit outweighs a budget that cannot provide the best possible standard of care. Imagine an Independent Family Council (first hand resident family members and friends) who can invest time at no cost performing surveys, studies and becoming part of the solution of expanding the consumer engagement of electronic tools so their information can be available to them

The use of Antipsychotic Drugs in the elderly

Three years ago when my mother became sepsis with a urinary track infection spending 5 days on I.V. antibiotics at Middlesex Hospital she was sent to recover at Saybrook where she eventually transitioned into long term care.

With her knee and hip replacements, her previous cardiac quadruple bypass, and her 2003 diagnosis of Parkinson's Disease, she could no longer take care of herself. She was in chronic pain from rheumatoid arthritis in her hands

and back surgery gone bad. Still Mom had a good sense of humor and knew she needed to do something. And she was afraid. Mom (Helen) stayed on the rehabilitation wing for the allowable time under Medicare. It took her 3 weeks to recover mentally from the UTI (urinary track infection). During that time she hallucinated, did not know where she was and did not make much sense talking. The care she received was very good. After 3 weeks when she became better, she was moved to another room still part of the rehabilitation unit. She received Physical Therapy and was able to walk with her wheeled walker. She became stronger but knew she could not return home. Two or three other Rehab patients shared a room with her and they got to go home. Helen was in transition from short to long term care. Her small daily dosage of Prozac prescribed by her personal Primary Care Doctor continued in the nursing home for depression. As Helen's disease worsened she had more anxiety. A roommate placement with someone who was able to independently walk but was hard of hearing and would often "yell" set the tone for added anxiety that my mother could not tolerate neurologically. She was starting to lose her ability to communicate. Not dementia. This was Parkinson's Disease, a disease where there is "flip-flopping" of words. Something called "tip of the tongue phenomenon", when you know what you want to say but the word comes out wrong. The medication she was taking for her Parkinson's needed to be adjusted because too much of it was causing delusions. Her neurologist put her on Seroquel 12.5 mg up to 3x day as needed. During this time the nursing home was sold and being taken over by a for-profit corporation. Renovations were taking place to have a "Grand Opening" to promote the new Rehabilitation Facility. The new owners made no renovations to the 3 long term units with the exception of keeping the continuity of the long hallway which divides the Rehabilitation Wing and one of the long term care wings. I was able to get Helen's room changed to one of those rooms since residents were being moved around to accommodate the renovations. The Seroquel Helen is given is an antipsychotic medication which unfortunately is a preferred drug for people with Parkinson's. It is a drug that benefits her at this most difficult stage in her disease. A very big problem is that since it is the only written prescription that can be given for anxiety up to 3x daily as needed sometimes it is given because Helen "appears" to have anxiety when in fact she is angry or upset and trying to tell someone she needs something. Consistent staff assignment is basically the only way to help someone like my mother. Consistent staff assignment cannot work unless you can have staff retention and you cannot achieve staff retention when the nursing assistants are shuffled around from one unit to another unit, or are not considered part of the team or are not listened to.
Substitute House Bill No. 5516, Public Act No. 12-30 AN ACT CONCERNING PRESCRIPTION DRUG ADMINISTRATION IN NURSING HOME FACILITIES states that "the medical director of a nursing home facility that implements a prescription drug formulary system may make a substitution for a drug prescribed to a patient of the facility in accordance with the provisions of this section"
Independent pharmacy consultants are not playing a role in the institutional pharmacy decision making process. The facility my mother resides just opened up an institutional in house pharmacy owned by the CEO's wife who also owns the Rehabilitation Physical Therapy business. Who will protect the choices being made with generic drugs being imported from other countries? Without an independent pharmacy consultant where is the disclosure of a reliable and stable workforce of pharmacy employees? This is a very bad conflict of interest when a pharmacy dispensing medications to its residents along with a medical director that may be able to substitute a lesser generic of unknown origin. A pharmacist told me that when your prescription is filled an electronic claim is sent to your insurance company. The drug is identified by its national drug code (NDC) and if the insurance company does not like the drug that is submitted, they reject the claim. The insurance company is the gatekeeper through their rejection process. The FDA considers the country of origin to be confidential information and in many cases the pharmacist cannot even tell where the drug was manufactured in order to advise patients who ask. Also if drugs are made for instance in India where they do not honor US drug patents or if the patent has expired and as a result drugs like Lipitor (atorvastatin) are made without FDA oversight, how do we know we are getting an identical drug?

Alice Bonner spoke of dementia care and **Alternatives to antipsychotic medication** stating "CMS is emphasizing

non-pharmacological alternatives for nursing home residents, including potential approaches such as consistent staff assignments, increased exercise or time outdoors, monitoring and managing acute and chronic pain, and planning individualized activities."

Special Committee on Aging'
Next Steps for Patient Safety: Assuring High Value Health Care Across All Sites of Care
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I say to you how will this happen without proper staff being scheduled? State surveyors look at self reporting staffing sheets instead of payroll records.

Nursing assistants, LPN's, unit supervisors are dedicated and would love nothing else than to take the best care of each resident. They do the best they can. A nursing home cannot give the highest quality of care, they cannot maintain a resident's ability to walk, and they cannot have true consistent assignment, or spend time with a resident when many bells are going off if there is not enough staff scheduled to work. In other words if you have one nursing assistant taking care of 12 or 14 or 15 residents, that one person has their hands full for their entire shift and does not, I repeat does not give direct care to all 12 or 14 or 15 residents. The same is true with a ratio of 1 aide to 10 or 11 residents. A ratio of 1 aide to 6-8 residents would not only provide the best care but would be cost effective. Research shows that the cost of replacing one aide is $3500.00. The staff retention problem would go away if aides could simply do their job instead of losing hours due to payroll cuts. The call outs would go away if aides were happy at their job. And they are not happy when they cannot be heard. When they know what a resident needs but it falls to deaf ears. When they have tried and tried but no one cares and corporate just wants to profit. The penalty must fit the crime.

Thank you for letting me voice my comments on such an important discussion I only wish I had the time to share my documentation with you but the deadline for submission is now.

Signed,
Gail R. Simon